IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	C.A. No. 20-2930-RGA [redacted]
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. HETERO USA INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT III, MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, Defendants.	PUBLIC VERSION FILED:August 20, 2024 C.A. No. 19-2053-RGA [redacted]
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, GERBERA THERAPEUTICS, INC., NANJING NORATECH PHARMACEUTICAL CO., LIMITED, Defendants.	C.A. No. 22-1395-RGA [redacted]

DECLARATION OF CHRISTOPHER A. VELLTURO, PH.D. CONCERNING IRREPARABLE HARM

I. OVERVIEW 1

A. QUALIFICATIONS AND EXPERIENCE 1
B. STATEMENT OF ASSIGNMENT 1
C. DOCUMENTS/MATERIALS CONSIDERED 2
D. SUMMARY OF CONCLUSIONS 3
E. DECLARATION STRUCTURE 5

II. MARKETPLACE AND ECONOMIC FACTS 5

A. THE PARTIES 5
1. Novartis 5
2. MSN 9
B. HEART FAILURE AND HEART FAILURE TREATMENTS 9
1. Heart Failure Background 9
2. Evolution in Treatment of Heart Failure 10
3. Growth of Emerging Heart Failure Treatments 12
C. PHARMACEUTICAL INDUSTRY CONTEXT 15
1. Insurance Coverage 16
2. Generic Competition 18
D. THE '659 AND '918 PATENTS AND NEXUS 21

III. IRREPARABLE HARM ASSESSMENT 21

A. DIRECT IMPACT OF GENERIC COMPETITION ON ENTRESTO® DURING AT-RISK LAUNCH PERIOD 22
1. Substantial Impact of Generic Entry 24
2. Irreparable Elements of Such Harm 26
B. ADDITIONAL HARMS 32
1. Continuing Harm to Entresto® Following Generic Withdrawal 32
2. Non-Compensable Harms to Other Product Lines 36

IV. CONSIDERATION OF BALANCE OF HARDSHIPS 37

V. CONSIDERATION OF PUBLIC INTEREST 38

I. OVERVIEW

A. Qualifications and Experience

1. I am the founder and president of Quantitative Economic Solutions, LLC, a microeconomic consulting firm. I received a Doctor of Philosophy degree (Ph.D.) in Economics from the Massachusetts Institute of Technology in Cambridge, Massachusetts in 1989. My fields of specialization include industrial organization and econometrics. My curriculum vitae, which lists my testimony for the last four years and my publications, is attached as Exhibit 16.

2. I have extensive experience in the valuation of intellectual property and in the assessment of economic injury/damages sustained as a result of copyright, trademark, and/or patent infringement. Industries that I have studied in this context include: pharmaceutical products, medical devices, over-the-counter medications and instruments, consumer products, computer hardware and software, semiconductors, and many others.

3. I have studied the pharmaceutical industry extensively and along a number of dimensions. From an intellectual property standpoint, I have analyzed patent infringement damages issues, commercial success and relevant nexus, and irreparable harm. I have also studied the pharmaceutical industry in the context of merger reviews in the United States and abroad, in private antitrust actions, and in the context of contract disputes. I have also evaluated pharmaceutical patent issues in the context of commercial success and injunctive relief considerations on numerous occasions, including evaluation of the possibility of irreparable harm arising from the "at-risk" launch of pharmaceutical products. I have previously served as an expert in damages assessment, economics generally, statistics/econometrics (including survey design and implementation), and as an expert on the pharmaceutical industry in particular.

B. Statement of Assignment

4. I have been asked by counsel for Novartis Pharmaceuticals Corporation ("Novartis") to assess whether Novartis would suffer substantial and irreparable harm if MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, MSN Life Sciences Private Limited ("MSN") were to launch "at risk" its sacubitril/valsartan products, which I understand are generic versions of Entresto® (Novartis's combination sacubitril/valsartan treatment for certain conditions relating to heart failure), and were then to withdraw its generic products from the marketplace as a result of a subsequent court decision

enjoining MSN from remaining in the market.[1] I have also been asked to assess economic issues relating to the balance of hardships between Novartis and MSN, and to the impact on the public interest stemming from a potential preliminary injunction.

5. For purposes of this declaration, Novartis's counsel has informed me that Novartis has asserted U.S. Patent No. 8,101,659 ("the '659 patent") against MSN, and that the validity of the '659 patent was tried to the District Court for the District of Delaware ("the District Court") in September 2022. The District Court on July 7, 2023 issued a decision invalidating the '659 patent. Novartis's counsel has also informed me that Novartis has asserted U.S. Patent No. 11,096,918 ("the '918 patent") against MSN, and that the infringement and validity of the '918 patent will be tried to the District Court in December 2024. I also understand that in July 2024, the FDA approved MSN's sacubitril/valsartan products. I have been asked to assume that, absent a preliminary injunction, an at-risk launch by MSN would occur on August 27, 2024.

6. Novartis's counsel has also informed me that a launch by MSN of its generic sacubitril/valsartan products "at risk" may also trigger the launch of generic sacubitril/valsartan products from other generic manufacturers, and that those generic sacubitril/valsartan products thereafter will remain on the market for several months until a potential subsequent Federal Circuit decision regarding the '659 patent enjoins them from remaining on the market. I have been asked to assume that such a decision would issue at the end of December, 2024. I have also been asked, alternatively, to assume that those generic sacubitril/valsartan products will remain on the market until a subsequent District Court decision on the '918 patent enjoins them from remaining on the market. I have been asked to assume such a decision would issue in May, 2025.

C. Documents/Materials Considered

7. In connection with this matter, I, or others working under my direction, have considered the following information:

- Financial documents, including sales and cost data produced by Novartis;
- Publicly available financial statements and other information about Novartis and MSN;
- Documents produced by Novartis relating to business strategy, pricing, and financial matters;

[1] QES is being compensated for my time spent on this matter at an hourly rate of $1,100, which is my customary rate. Payment is not contingent on the outcome of this matter. QES is also compensated for the time spent on this matter by persons working at my direction at rates lower than my hourly rate.

- Produced and/or publicly available marketing materials and product information for Entresto®;
- Conversations with:
  - Ms. Kristin Miller, Novartis Vice President and General Manager – Pelacarsen and Heart Failure;
  - Mr. Robert Rubinsky, Novartis Chief Market Access Officer;
  - Mr. Daniel DiMeo, Novartis Executive Director, National Accounts & Pricing Strategy;
  - Ms. Ashley Reid, Novartis Director, General Management and Product Strategy for Business Planning and Analysis; and
  - Mr. Amogh Purandare, Associate Director, Forecasting.

A complete list of the information I considered in forming my opinions can be found in Exhibit 17 to this declaration.

8. My findings at this point are based on the information available to me. I may revise or supplement my opinions based on additional discovery and analyses. I may also provide additional analyses (including, but not limited to, additional expert declarations) if I am called upon to do so, including a response to any opinions offered by experts on behalf of MSN.

D. Summary of Conclusions

9. The primary question underlying an irreparable harm inquiry is whether a later award of monetary damages will be sufficient to compensate the patentee for the impact of the infringement sought to be enjoined. Irreparable harm can be present in cases where complexities in the marketplace and/or the nature of the harms make damages difficult to fully quantify. Irreparable harm can also be present in cases where the introduction of an infringing product will have significant and persistent effects on the patentee and/or on the marketplace into which the patentee sells its products. For example, patent damages, which typically focus on only some past harms, are highly unlikely to compensate a patentee for potential future harms. Further, irreparable harm can exist if a defendant is unable to pay a potential monetary judgment, as the patentee cannot be made whole. Based on my experience and the evidence set forward in this declaration, I have determined that these conditions are met in the present case, and therefore that Novartis would suffer substantial and irreparable harm along multiple dimensions if MSN were to launch its generic competitor to Entresto®.

10. As an initial matter, the revenues and profits driven by Entresto® sales are of central importance to Novartis. In the U.S. in 2023 alone, Entresto® generated more than $3 billion in net sales – well beyond the billion-dollar threshold historically used to classify "blockbuster" drugs. In 2022, Entresto® global net sales overtook those of Novartis's Cosentyx®, making Entresto® Novartis's best-selling individual drug globally at present. Moreover, particular aspects of the marketplace for heart failure medications – including its overall growth as undiagnosed or untreated patients are increasingly diagnosed and treated, the shift from historical standards of care to Entresto®, and general marketplace dynamics associated with generic pharmaceutical substitution – make it likely that the impacts of MSN's generic entry will persist even if MSN were to subsequently withdraw its products from the marketplace as a result of an ultimate injunction. These product and marketplace characteristics would result in damages sustained following the potential issuance of a permanent injunction that would lead to the removal of the generic, as well as damages during the pendency of an at-risk launch that would be difficult to fully quantify.

11. Below is a brief description of these forms of irreparable harm, which I discuss at length further in this declaration:

- In the face of generic entry, Novartis will suffer some combination of immediate and substantial sales volume losses and/or price erosion on its retained volumes. The ultimate impact on Novartis's profit is likely to be massive – both immediately and in the medium term;
- Because of Entresto®'s consistent and significant overperformance, Novartis has had historical difficulty reliably forecasting the full extent of future Entresto® sales levels. Given Entresto®'s marketplace momentum has continued through the present, it is likely any existing forecasts of Entresto® sales in the coming months and years will understate its actual sales levels in a world but for 2024 generic entry. Without a reliable estimate of Novartis's full "but-for" net sales – a key input into a potential damages analysis – a full and reliable quantification of Novartis's lost profits would be extremely difficult at a future date;
- Notwithstanding the precise amount of Novartis's prospective lost profits due to generic entry, it is clear that the general order of magnitude of the harm will be large, even during the limited period of a prospective at-risk launch in the latter half of 2024. Given MSN's public statements about its own financials, it is unclear whether MSN would be in a position to readily pay a damages judgment, should one be issued against them;
- Moreover, I understand that, in the face of a 2024 at-risk generic launch, Novartis may accelerate its planned reduction of its physician education/promotion efforts and patient support programs. Such an accelerated reduction would have a long-lasting impact both on Entresto®'s profitability into 2025, as well as on Novartis's other cardiology products – Leqvio® and the forthcoming pelacarsen – well into the future.

12. With respect to the balance of hardships, I find the potential harm faced by MSN from delayed entry under an injunction is significantly outweighed by the harm Novartis would likely incur from generic entry. Given the generally lower per-unit price of a generic product vis-à-vis the brand, MSN's profits will be lower than the per-unit losses Novartis would sustain. Furthermore, if MSN's generic entry creates a "jailbreak scenario" where additional generics also enter the marketplace, then the sales volumes captured by MSN will only represent a portion of the sales losses that Novartis will incur. Additionally, Novartis will suffer harms that would not only take place during the pending litigation, but also extend well beyond MSN's (or any further generic entrants') subsequent withdrawal.

13. Finally, I find that the public interest considerations weigh in favor of Novartis. In general, patent protection for novel therapeutic products affords innovative drug companies the ability to recoup their substantial investments in research and development. In this instance, any potential decrease in investment in education, awareness, and patient support programs for Entresto® by Novartis in the face of generic entry will adversely impact patients. Additionally, any loss of or decrease to support programs would negatively impact both patients who are currently on Entresto®, and patients who will start on and may stop treatment prematurely absent support from Novartis.

E. Declaration Structure

14. The remainder of this declaration is structured as follows: In Section II, I provide background on heart failure, a discussion of marketplace dynamics among heart failure treatments, and relevant background on the pharmaceutical industry in general. In Section III, I provide my opinions and analysis related to my assessment of irreparable harm. In Section IV, I consider the balance of hardships associated with a potential preliminary injunction, and in Section V, I discuss public interest considerations.

II. MARKETPLACE AND ECONOMIC FACTS

A. The Parties

1. Novartis

15. As background, Novartis AG is a global healthcare company that was founded in 1996 through the merger of Ciba-Geigy AG and Sandoz AG, two chemicals companies founded in Basel,

Switzerland.[2] Plaintiff Novartis Pharmaceuticals Corporation, headquartered in East Hanover, New Jersey, operates as a subsidiary of Novartis AG[3] and markets and sells various medicines and treatments for helping patients and improving patient care.[4] I use "Novartis" to refer to one or both of these entities, unless where a distinction is called for.

16. Novartis is an innovative drug company.[5] Several of Novartis's major products are protected by patent and other intellectual property rights, giving Novartis the opportunity to recoup its substantial investments in research and development. For instance, in its 2023 annual report, Novartis noted that loss of patent exclusivity for one or more patented products – such as Entresto® – may have a material adverse effect on its operations.[6]

17. Novartis makes continuous efforts to innovate and achieve additional regulatory approvals for its products. According to its 2023 annual report, Novartis spent more than $11 billion on research and development ("R&D") in 2023, amounting to approximately 25 percent of its net sales.[7] Indeed, Novartis has over 60 products or projects in Phase I or II trials and over 40 products or projects in Phase III or undergoing registration.[8]

18. In 2023, Novartis generated net sales from continuing operations of more than $45 billion.[9] Novartis markets five categories of key products: Cardiovascular, renal and metabolic (collectively, "cardiovascular"), Immunology, Neuroscience, Oncology, and Established Brands.[10] As disclosed in Novartis's annual report, the cardiovascular category generated approximately $6.4 billion in net sales worldwide in 2023.[11] Of those sales, the vast majority were generated by Entresto®, and

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[2] https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf, p. 21; https://www.novartis.com/us-en/about/company-history.
[3] https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf, pp. 38-39, F-73-F-74.
[4] *See, e.g.*, https://www.novartis.com/us-en/about/novartis-us; https://www.novartis.com/about.
[5] https://www.novartis.com/about
[6] https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf, pp. 11-12.
[7] I calculate the percentage of net sales by dividing research and development ($11,371 million) by net sales to third parties from continuing operations ($44,635 million), yielding 25.5%. *See* https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf, pp. F-1, F-16.
[8] https://www.novartis.com/about/innovative-medicines; https://www.novartis.com/research-and-development; https://www.novartis.com/research-development/novartis-pipeline.
[9] https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf, pp. 22, F-16.
[10] https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf, pp. 22-25.
[11] https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf, p. F-18.

more than half were U.S. sales.[12] The cardiovascular category also includes a newer Novartis product, Leqvio®, which received FDA approval in 2021.[13]

19. Entresto® is a combination of sacubitril, a neprilysin inhibitor, and valsartan, an angiotensin II receptor blocker.[14] It was initially approved by the FDA in 2015 and was indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure and reduced ejection fraction ("HFrEF").[15] Left ventricular ejection fraction ("LVEF") is a measure of the percentage of the total amount of blood in the heart that is pumped out from the left ventricle with each heartbeat.[16] In 2021, the FDA granted Entresto® an expanded indication that I understand includes not only chronic heart failure patients with LVEF of less than or equal to 40%, but also those with LVEF greater than 40%, including those with preserved ejection fraction ("HFpEF").[17] As a result, I understand Entresto® is now approved to treat all patients with chronic heart failure.[18] Entresto® is the only angiotensin receptor/neprilysin inhibitor ("ARNi") drug currently available.[19] As discussed further in Section II.B, other prescription medications historically used to treat heart failure include angiotensin-converting enzyme inhibitors ("ACEis"), angiotensin II receptor blockers ("ARBs"), and sodium-glucose cotransporter-2 inhibitors ("SGLT2is"), among others.[20] As discussed therein, I understand recent clinical guidelines have generally shown preference for Entresto® over these other treatments in many circumstances.

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[12] https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf, pp. F-18, F-19.
[13] https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2022.pdf, pp. 22-23, F-22; https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214012lbl.pdf, p. 1.
[14] https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207620Orig1s000lbl.pdf, p. 1.
[15] https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207620Orig1s000lbl.pdf, pp. 1, 8.
[16] https://www.pennmedicine.org/updates/blogs/heart-and-vascular-blog/2022/april/ejection-fraction-what-the-numbers-mean; https://my.clevelandclinic.org/health/articles/16950-ejection-fraction.
[17] https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207620Orig1s000lbl.pdf, p. 1; https://www.novartis.com/us-en/news/media-releases/novartis-entresto-granted-expanded-indication-chronic-heart-failure-fda; https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/207620s018lbl.pdf; Verified Complaint, Novartis Pharmaceuticals Corporation v. Xavier Becerra and Robert M. Califf, M.D., Case 1:24-cv-02234, 07/30/24 (Dkt. 1), ¶ 30.
[18] https://www.novartis.com/us-en/news/media-releases/novartis-entresto-granted-expanded-indication-chronic-heart-failure-fda; https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/207620s018lbl.pdf.
[19] https://my.clevelandclinic.org/health/treatments/23939-angiotensin-receptor-neprilysin-inhibitor-arni; https://www.ncbi.nlm.nih.gov/books/NBK507904; https://www.mayoclinic.org/diseases-conditions/heart-failure/diagnosis-treatment/drc-20373148.
[20] https://www.mayoclinic.org/diseases-conditions/heart-failure/diagnosis-treatment/drc-20373148

20. Novartis financial data indicate that Entresto® sales have grown dramatically since its launch in 2015, making it a top selling drug not just in cardiovascular care, but more broadly as well.[21] Entresto® has generated more than $23 billion in cumulative worldwide net sales from its initial launch in 2015 through the second quarter of 2024.[22] On this worldwide basis, Entresto® has been among Novartis's three best-selling products since 2020, and it became Novartis's best-selling drug in the fourth quarter of 2022, when it surpassed Cosentyx®.[23] In the U.S., Entresto® has generated more than $12 billion in cumulative net sales from its initial launch in July 2015 through June 2024, including $0.6 billion in 2018, $0.9 billion in 2019, $1.3 billion in 2020, $1.7 billion in

[21] This is true both within Novartis, and more broadly globally, *see* https://www.drugdiscoverytrends.com/best-selling-pharmaceuticals-2023/.

[22] ($21 million + $170 million + $507 million + $1,028 million + $1,726 million + $2,497 million + $3,548 million + $4,644 million + $6,035 million + $1,879 million + $1,898 million) = $23,953 million, *see*
https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2015-en.pdf, p. 189;
https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2016-en.pdf, p. 198;
https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2017-en.pdf, p. 206;
https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2018-en.pdf, p. F-24;
https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2019.pdf, p. F-27;
https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2020.pdf, p. F-24;
https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2021.pdf, p. F-24;
https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2022.pdf, p. F-22;
https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf, p. F-19;
https://www.novartis.com/sites/novartis_com/files/q1-2024-investor-presentation.pdf, p. 6;
https://www.novartis.com/sites/novartis_com/files/2024-07-interim-financial-report-en.pdf, p. 37.

[23] https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2020.pdf, pp. F-25, F-26;
https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2021.pdf, pp. F-25, F-26;
https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2022.pdf, p. F-23;
https://www.novartis.com/sites/novartis_com/files/q4-2022-media-release-en.pdf, p. 4. Novartis's 2023 annual report shows Entresto® remains Novartis's top-selling drug, see https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf, p. F-19; https://www.novartis.com/sites/novartis_com/files/q4-2023-media-release-en.pdf, p. 4.

2021, $2.4 billion in 2022, $3.1 billion in 2023, and $1.9 billion in the first half of 2024.[24] In recent years, Novartis has consistently ranked Entresto® as its top "key growth driver."[25]

2. MSN

21. MSN Pharmaceuticals, established in 2014, is located in Piscataway, New Jersey as a fully owned subsidiary of MSN Group / MSN Laboratories, which was founded in 2003 and is headquartered in Telangana, India.[26] MSN develops and manufactures products for MSN Group in addition to specializing in manufacturing of generic pharmaceutical products.[27] I understand that MSN is one of the Defendants in the above captioned matters.

B. Heart Failure and Heart Failure Treatments

1. Heart Failure Background

22. I am not a person of ordinary skill in the art ("POSA") as that term has been defined by Novartis and Defendants in these proceedings, and do not hold myself out as an expert on the treatment of heart failure. I have provided the information in this section solely as background for my economic analysis of the irreparable harm that Novartis will sustain due to generic entry.

23. Heart failure is a clinical syndrome with symptoms and signs resulting from structural or functional impairment of ventricular filling or ejection of blood.[28] Depending on the progression

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[24] ($0.021 billion + $0.17 billion + $0.3 billion + $0.56 billion + $0.9 billion + $1.3 billion + $1.7 billion + $2.4 billion + $3.1 billion + $1.9 billion) = $12.4 billion. Novartis reports U.S. segmented net sales of Entresto® beginning only in 2017 (reported in Novartis's 2018 annual report). I therefore assume pre-2017 Entresto® net sales are U.S. net sales. *See* https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2015-en.pdf, p. 189; https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2016-en.pdf, p. 198; https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2017-en.pdf, p. 206; https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2018-en.pdf, p. F-25; https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2019.pdf, p. F-28; https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2020.pdf, p. F-25; https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2021.pdf, p. F-25; https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2022.pdf, p. F-23; https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf, p. F-19; https://www.novartis.com/sites/novartis_com/files/2024-07-interim-financial-report-en.pdf, p. 38.

[25] Novartis has ranked its key growth drivers in order of contribution to growth since Q2 2021. *See* https://www.novartis.com/sites/novartis_com/files/q2-2021-media-release-en.pdf, p. 3. *See also, e.g.,* https://www.novartis.com/sites/novartis_com/files/q4-2021-media-release-en.pdf, p. 3; https://www.novartis.com/sites/novartis_com/files/q4-2022-media-release-en.pdf, p. 3; https://www.novartis.com/sites/novartis_com/files/q4-2023-media-release-en.pdf, p. 4.

[26] http://www.msnlabs.com/who-we-are.html; http://msnpi.com; https://www.linkedin.com/company/msnlabs/.

[27] http://msnpi.com; http://www.msnlabs.com/who-we-are.html.

[28] https://www.mayoclinic.org/diseases-conditions/heart-failure/symptoms-causes/syc-20373142

of heart failure, treatments in each stage aim to modify risk factors, treat risk and structural heart disease to prevent heart failure, and reduce symptoms, morbidity, and mortality.[29] The 2022 American Heart Association ("AHA"), American College of Cardiology ("ACC"), and Heart Failure Society of America ("HFSA") Guideline for the Management of Heart Failure ("AHA/ACC/HFSA guideline"), the most recent guideline available, classifies heart failure patients into groups including patients with "HFrEF" and patients with "HFpEF," which together constitute the vast majority of heart failure patients.[30]

24. I understand the most common medications to treat heart failure include the historically used ACEis, ARBs, and the more recently emergent ARNis and SGLT2is.[31] Below, I review these categories of treatments in more detail.

2. Evolution in Treatment of Heart Failure

25. Renin-angiotensin-aldosterone system inhibitors ("RAASis") are heart failure drugs.[32] One type of RAASi – "ACEis" – had historically been considered the cornerstone of treatment for patients with HFrEF.[33] As of April 2024, there are 10 FDA-approved ACEis: benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, perindopril, quinapril, ramipril, and trandolapril.[34] ARBs, which are also RAASis, have also been used to treat patients with HFrEF.[35] ARBs include azilsartan medoxomil (Edarbi®), candesartan, eprosartan mesylate,[36] irbesartan, losartan potassium, olmesartan, telmisartan, and valsartan.[37] An ARNi comprises two drugs administered in

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[29] https://www.mayoclinic.org/diseases-conditions/heart-failure/symptoms-causes/syc-20373142
[30] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5494150; https://www.jacc.org/doi/10.1016/j.jacc.2021.12.012; https://pubmed.ncbi.nlm.nih.gov/32749493; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3870014.
[31] Conversation with Kristin Miller. I also understand that several other categories of treatments may be used to treat certain forms of heart failure, including beta blockers, mineralocorticoid receptor antagonists ("MRAs"), hydralazine and isosorbide dinitrate, diuretics, I_f channel blocker, soluble guanylate cyclase ("sGC") stimulators, and others. *See* https://www.heart.org/en/health-topics/heart-failure/treatment-options-for-heart-failure/medications-used-to-treat-heart-failure; https://www.jacc.org/doi/10.1016/j.jacc.2021.12.012.
[32] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7101821
[33] https://www.ccjm.org/content/86/9/608
[34] https://www.mayoclinic.org/diseases-conditions/high-blood-pressure/in-depth/ace-inhibitors/art-20047480. *See also*, https://www.drugs.com/drug-class/angiotensin-converting-enzyme-inhibitors.html.
[35] https://www.ccjm.org/content/86/9/608
[36] Though an FDA Abbreviated New Drug Application ("ANDA") for a generic eprosartan mesylate received a completed review and approval in 2011, both generic and branded eprosartan mesylate, Teveten®, were discontinued. *See* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/202012s000ltr.pdf; https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202012; https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020738; https://www.drugs.com/availability/generic-teveten.html.
[37] https://my.clevelandclinic.org/health/drugs/23327-angiotensin-ii-receptor-blockers

combination to treat heart failure – an ARB and a neprilysin inhibitor.[38] Sacubitril/valsartan (Entresto®) is the only ARNi drug currently available.[39]

26. Recent clinical evidence regarding the superior efficacy of ARNis (i.e., Entresto®)[40] has triggered a shift in clinical guidelines for RAASis for treatment of heart failure. In particular, the 2022 AHA/ACC/HFSA guideline recommends Entresto® as the preferred Class 1 first-line treatment for patients with HFrEF, while their 2013 guideline had previously only included ACEis and ARBs (in certain patients) as recommended RAASis.[41] The 2022 AHA/ACC/HFSA guideline also recommends Entresto® as a replacement for certain patients who tolerate ACEis and ARBs.[42] Additionally, the 2023 American College of Cardiology Expert Consensus Decision Pathway on the management of HFpEF updated the treatment algorithm for HFpEF patients to only use ARBs in "ARNI-eligible individuals who cannot take due to cost or intolerance."[43] Similarly, the latest 2024 American College of Cardiology Expert Consensus Decision Pathway for treatment of HFrEF updated the treatment algorithm for guideline-directed medical therapy to state that "ACE inhibitors/ARBs should only be considered in patients with contraindications, intolerance, or inaccessibility to ARNI."[44]

27. In February 2021, the FDA approved Entresto®'s expanded indication incorporating patients with HFpEF, making Entresto® the first heart therapy with an FDA-approved indication that includes patients with preserved ejection fraction.[45] The Novartis-sponsored PARAGLIDE-HF clinical trial was completed at the end of 2022, and in February of 2023, evidence about the safety, tolerability, and efficacy of Entresto® as compared to valsartan in patients with a recent worsening heart failure event was published.[46] Evidence from the PARAGLIDE-HF trial supports a larger

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[38] https://my.clevelandclinic.org/health/treatments/23939-angiotensin-receptor-neprilysin-inhibitor-arni
[39] https://my.clevelandclinic.org/health/treatments/23939-angiotensin-receptor-neprilysin-inhibitor-arni
[40] For example, Entresto®'s label reports the results of the PARADIGM-HF clinical trial, demonstrating Entresto®'s superiority compared to enalapril, an ACEi. *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/207620s018lbl.pdf, pp. 5, 13.
[41] https://www.jacc.org/doi/10.1016/j.jacc.2021.12.012; https://www.ahajournals.org/doi/full/10.1161/CIR.0b013e31829e8776.
[42] "Class 1" represents strong recommendations. *See* https://www.jacc.org/doi/10.1016/j.jacc.2021.12.012. Other medical publications also share this view that ARNis should replace ACEis and ARBs for certain patients. *See*, *e.g.*, https://www.eurekaselect.com/article/130202.
[43] https://www.jacc.org/doi/10.1016/j.jacc.2023.03.393, Figure 9.
[44] https://www.jacc.org/doi/10.1016/j.jacc.2023.12.024, Figure 2.
[45] https://www.sciencedirect.com/science/article/pii/S075333222101249X
[46] https://www.sciencedirect.com/science/article/pii/S1071916423000404

use of Entresto® in patients with an ejection fraction above 40%, and suggests that an ARNi should be a part of foundational therapy for HF patients.[47]

28. Recently, the SGLT2is class of drugs, initially approved for treatment of type 2 diabetes, have been approved for – and increasingly used to treat – heart failure.[48] SGLT2is have demonstrated benefits for the treatment of heart failure irrespective of whether the patient has diabetes.[49] SGLT2is include empagliflozin (Jardiance®), canagliflozin (Invokana®), dapagliflozin (Farxiga®), and sotagliflozin (Inpefa®).[50] Drugs in this class have continued to receive FDA approval for heart failure related indications. For example, empagliflozin (Jardiance®), dapagliflozin (Farxiga®), and sotagliflozin (Inpefa®) all received FDA approval for a wider patient population with heart failure between February of 2022 and May of 2023.[51]

3. Growth of Emerging Heart Failure Treatments

29. I understand that before Entresto®, ACEis were historically considered the cornerstone of treatment for patients with HFrEF, while ARBs were also commonly used to treat patients with HFrEF.[52] No drug had been FDA approved to treat any HFpEF patients before Entresto® (an ARNi) was approved in February 2021.[53] Early Novartis business planning documents for Entresto® characterized the marketplace for heart failure treatments in the mid-2010s as "largely

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[47] https://www.tctmd.com/news/more-arni-insights-fortify-role-below-normal-lvef-paraglide-hf. *See also*, https://www.jacc.org/doi/10.1016/j.jacc.2023.04.019; https://academic.oup.com/eurheartj/advance-article/doi/10.1093/eurheartj/ehad344/7173308.
[48] https://www.medpagetoday.com/cardiology/chf/102393
[49] https://www.jacc.org/doi/10.1016/j.jacc.2021.12.012
[50] https://www.drugs.com/drug-class/sglt-2-inhibitors.html; https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204629s033lbl.pdf; https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/INVOKANA-pi.pdf; https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202293s021lbl.pdf; https://www.lexpharma.com/inpefa-US-PI.pdf.
[51] Jardiance®, Inpefa®, and Farxiga® all received FDA approval for expanded indications including HFpEF between February 2022 – May 2023. All are approved for HFrEF patients as well. *See* https://www.ajmc.com/view/fda-approves-empagliflozin-for-broader-type-of-heart-failure; https://www.biospace.com/article/releases/lexicon-announces-fda-approval-of-inpefa-sotagliflozin-for-treatment-of-heart-failure; https://www.astrazeneca-us.com/media/press-releases/2023/farxiga-extended-in-the-us-to-reduce-risk-of-cardiovascular-death-and-hospitalization-for-heart-failure-to-a-broader-range-of-patients-05092023.html; https://www.fiercepharma.com/pharma/fda-nod-astrazenecas-farxiga-gains-ground-heart-failure-race-jardiance.
[52] *See* Section II.B.2.
[53] https://www.tctmd.com/news/new-fda-indication-opens-use-sacubitrilvalsartan-hfpef; https://www.novartis.com/news/media-releases/novartis-entresto-granted-expanded-indication-chronic-heart-failure-fda.

static," with elements of "physician inertia"[54] and physician "attachment to ACEi."[55] In light of these observations, Novartis recognized the need for a "[m]assive [heart failure] education effort"[56] to build the Entresto® brand and explain the significant new benefits of Entresto®.

30. Since then, as shown in Figure 1, below, both Entresto® and SGLT2is (collectively) have made considerable inroads among heart failure patients in the U.S., which I understand is largely due to guideline updates in recent years (e.g., designations of "Class 1" treatments for HFrEF patients, and for Entresto® in particular, its designation as not only a Class 1 treatment in general, but as a replacement for certain patients on ACEis and ARBs[57]). As shown, Entresto® and SGLT2is have generated considerable prescription share in the broad heart failure treatment marketplace largely at the expense of ACEis in particular, but also to some extent at the expense of ARBs. This figure demonstrates that the material advances in Entresto®'s commercial performance were significantly driven by increased marketplace penetration and acceptance.

[54] Ex. 8, NPC-VS-016634221 at 231, 240.
[55] Ex. 9, NPC-VS-016672420 at 421.
[56] Ex. 9, NPC-VS-016672420 at 424.
[57] Conversation with Kristin Miller. https://www.jacc.org/doi/10.1016/j.jacc.2021.12.012.

Figure 1: IQVIA-Estimated Heart Failure U.S. Prescriptions by Treatment Class
July 2015 – March 2024 (thousands, 3-month rolling average)
Source: Exhibit 12-B

31. I understand the heart failure treatment field in the U.S. is projected to continue its recent (since 2020) growth trajectory and more than double in dollar terms between 2022 and 2030.[58] I understand this trend is attributable to multiple factors. First, the underlying patient population for such treatments is growing. For example, as of November 2022, Novartis estimated that there were 7.23 million patients with heart failure in the U.S., a number that represents 2% growth year-over-year.[59] There are approximately 1 million new heart failure patients per year in the U.S. due largely to the aging of the population.[60] Further, the U.S. is experiencing an increasing burden of diseases that contribute to heart failure, such as obesity, diabetes, hypertension, chronic pulmonary

[58] https://www.grandviewresearch.com/industry-analysis/congestive-heart-failure-drugs-market-report, *see* "U.S. Congestive Heart Failure Drugs Market." A 14.3% compound annual growth rate ("CAGR") across 2022 – 2030 more than doubles the initial amount. ((1 + 0.143) ^ 8) = 2.91.
[59] Conversation with Kristin Miller. *See also*, Ex. 1, 2023 Prioritizing Entresto's Marketing Strategy_11_11_22 pre-read.pdf, p. 8.
[60] Heidenreich, Paul, Greg Fonarow, Yekaterina Opsha et al. "Economic Issues in Heart Failure in the United States," Heart Failure Society of America Review, Vol 28 Issue 4 (2022): 453-466 (available at https://www.onlinejcf.com/article/S1071-9164(22)00001-X/fulltext).

diseases, and renal diseases.[61] The prevalence of heart failure in the U.S. from 2017 to 2020 was 6.7 million among those older than 20 years old.[62] By 2030 in the U.S., it is estimated that more than 8 million individuals will have heart failure, implying a prevalence rate of 1 in every 33 individuals.[63] Finally, the introduction and uptake of newer heart failure treatments (including Entresto®) have increased survival rates of patients with heart failure.[64] Thus, as more heart failure patients transition to, or start on efficacious treatments, the overall patient population will continue to increase.

32. Second, I understand that undiagnosed, misdiagnosed, or untreated patient populations have increasingly been put on treatment in recent years, and that these trends are expected to continue in at least the short-to-medium term.[65] Indeed, in its [redacted].[66] Consistent with this estimate, a 2021 study published in the Journal of Cardiac Failure found that the misdiagnosis of heart failure ranges from approximately 16% to 68% in hospital and general practitioner settings, respectively.[67] Furthermore, this study found that among a cohort of patients with chronic obstructive pulmonary disease, heart failure was unrecognized in more than 20% of patients.[68] I understand that Novartis, in particular, has and continues to devote resources to education and promotion initiatives targeting these undiagnosed or untreated patient populations (and their corresponding prescribing physicians).[69]

C. Pharmaceutical Industry Context

33. The U.S. pharmaceutical industry has a number of characteristics that are central to understanding the nature and breadth of irreparable harm likely to be suffered by Novartis in the event of generic entry. Drug development and commercialization is an expensive, time consuming, and risky

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[61] https://www.grandviewresearch.com/industry-analysis/congestive-heart-failure-drugs-market-report
[62] https://www.ahajournals.org/doi/epub/10.1161/CIR.0000000000001209, Table 22-2.
[63] Heidenreich, Paul, Greg Fonarow, Yekaterina Opsha et al. "Economic Issues in Heart Failure in the United States," Heart Failure Society of America Review, Vol 28 Issue 4 (2022): 453-466 (available at https://www.onlinejcf.com/article/S1071-9164(22)00001-X/fulltext).
[64] https://www.nejm.org/doi/full/10.1056/NEJMc1509753; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6919428; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7643567; https://www.webmd.com/heart-disease/heart-failure/features/advances-heart-failure.
[65] Conversation with Kristin Miller.
[66] Ex. 10, NPC-VS-016683138 at 159.
[67] https://www.onlinejcf.com/article/S1071-9164(21)00204-9/fulltext
[68] https://www.onlinejcf.com/article/S1071-9164(21)00204-9/fulltext
[69] Conversation with Kristin Miller.

exercise, which places inordinate pressure on suppliers to maximize revenues on the few drugs that achieve widespread commercial significance.[70] The revenue opportunities associated with novel pharmaceutical products are facing downward pressure from the demand side, as payers face mounting pressures to control costs and thus have developed increasingly sophisticated strategies to help steer doctors and patients to what the payers believe are more cost-effective therapy choices.[71] Also, from a policy standpoint, regulatory frameworks aimed at accelerating the adoption of generic drugs quickly and comprehensively have been put in place at the U.S. federal level and in essentially every state.[72] These factors place significant pressure on developers/suppliers to bring innovative drugs to market and to market them effectively during their limited periods of exclusivity.

1. Insurance Coverage

34. In the U.S., the vast majority of the population has some form of health insurance coverage to finance their healthcare expenditures, which include prescription drug spending.[73] Health insurers serve as third parties who pay providers on behalf of patients. These third-party payers ("TPPs") include employment-based private insurance plans, managed care organizations ("MCOs"), and federal programs such as Medicare or Medicaid.[74] Private insurers, Medicare, and Medicaid account for a majority of spending on prescription drugs.[75] Payers balance the generosity of their pharmacy benefit in terms of cost-sharing and breadth of coverage against the cost.[76]

35. Pharmacy benefit managers ("PBMs") manage prescription drugs expenses on behalf of health care payers. PBMs handle prescription billing, negotiate drug prices with drug suppliers, and

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[70] *See, e.g.*, https://www.cbo.gov/publication/57126.
[71] *See*, *e.g.*, https://www.uhc.com/employer/news-strategies/resources/prioritizing-pharmacy-care-costs. The Inflation Reduction Act of 2022 includes several provisions to lower prescription drug costs for Medicare beneficiaries and reduce prescription drug spending by the federal government. *See also,* https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries.
[72] https://www.whitecase.com/insight-alert/2022-drug-pricing-update-states-continue-legislative-push-even-congress-passes-long. Generic substitution is permitted by law in 31 out of the 50 states and in the District of Columbia. Generic substitution is mandated by law in an additional 19 states/territories, *see* Sacks, Chana A., Victor L. Van de Wiele, and Lisa A. Fulchino, "Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions," *JAMA Internal Medicine* vol. 181(1) (2021): 16-22 (available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7489381).
[73] https://www.cdc.gov/nchs/data/nhis/earlyrelease/insur202205.pdf
[74] https://sgp.fas.org/crs/misc/R40834.pdf
[75] https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid
[76] https://www.rand.org/content/dam/rand/pubs/research_reports/RRA300/RRA328-1/RAND_RRA328-1.pdf, p. 5

create retail pharmacy networks.[77] PBMs also design and maintain formularies, which are lists of drugs covered by the insurance plan that determine where prescription drugs can be filled and patients' out-of-pocket costs, and utilization management tools.[78]

36. An important aspect of a pharmaceutical product's competitive position is its position (or "tier") in these formularies. Formularies are typically divided into tiers based on drug characteristics, price, and other considerations. Tiers determine the level of cost-sharing patients must contribute when they fill their prescriptions. A drug on a lower, more-preferred tier (e.g., tier 1) is typically associated with lower cost-sharing requirements than drugs placed on higher, less-preferred tiers. Tier 1 is typically associated with generics, while top tiers involve specialty products.[79] Some drugs are simply not covered under some formularies, in which case the patient bears the entire burden of paying for the drug.

37. Once a generic equivalent of a branded drug becomes available, the generic drug is typically placed in a preferred position on a formulary as compared to the branded drug. For example, the generic is commonly placed on tier 1, while the branded drug is downgraded to a non-preferred tier and often excluded from formulary coverage altogether.[80] As I discuss below, the rapid downgrade in formulary position – in combination with other factors – leads to steep and immediate losses in sales volumes for branded products upon the entry of generic equivalents.

38. The highly consolidated nature of the PBM marketplace means that PBMs have concentrated negotiating power vis-à-vis drug manufacturers. In 2022, three PBMs (Caremark, Express Scripts, and OptumRx) handled an estimated nearly 80 percent of total equivalent prescription claims in the U.S.[81] From 2014 to 2022, 1,357 unique prescription drugs were excluded from standard formularies by one or more of these three PBMs for at least 1 year. Of these, 654 were single-

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[77] https://www.rand.org/content/dam/rand/pubs/research_reports/RRA300/RRA328-1/RAND_RRA328-1.pdf, p. 5
[78] https://www.commonwealthfund.org/sites/default/files/2019-03/Seeley_pharmacy_benefit_managers_ib.pdf, p. 2
[79] https://www.healthaffairs.org/do/10.1377/hpb20171409.000177. *See also,* https://www.rand.org/content/dam/rand/pubs/research_reports/RRA300/RRA328-1/RAND_RRA328-1.pdf.
[80] *See, e.g.*, Dusetzina, Stacie B., Juliette Cubanski, Leonce Nshuti, Sarah True, Jack Hoadley, Drew Roberts, and Tricia Neuman. "Medicare Part D Plans Rarely Cover Brand-Name Drugs When Generics Are Available: Study examines Medicare Part D coverage to quantify how often brand-name drugs are designated preferred over generics," *Health Affairs* 39, no. 8 (2020): 1326-1333 (available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9297534). Conversation with Robert Rubinsky and Daniel DiMeo.
[81] https://www.drugchannels.net/2023/05/the-top-pharmacy-benefit-managers-of.html

source branded drugs.[82] In conjunction with formularies, PBMs also use prior authorization, step therapy, and quantity limits to restrict use of a particular drug or limit how much a drug can be dispensed for one prescription.[83]

39. Factors specific to the cardiovascular treatment space further exacerbate pricing pressures from payers. Payers appear to have lower tolerance of high pricing for cardiovascular medications than for oncology.[84] The large size of the target cardiovascular disease populations may incur higher costs than the target populations of more specialized products.[85] Further, cardiovascular drugs are not designated by Medicare as one of the six legally protected classes requiring payer coverage.[86] Entresto® itself was subject to cost-control mechanisms by health plans in the past. For example, in February 2018, a majority of Virginia payers required prior authorization for Entresto®.[87]

2. Generic Competition

40. Generic entry invariably has a profound effect on the demand (from a quantity and price perspective) of the corresponding branded drug, ultimately leading to the virtual extinction of the brand. Indeed, studies of the effect of generic entry indicate that the volume share of the branded reference drug typically declines by 40 to 80 percent within six months of generic entry and up to 90 percent within two years.[88] Furthermore, the speed with which generic entrants capture share

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[82] https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf, pp. 2-3.
[83] https://www.healthaffairs.org/do/10.1377/hpb20171409.000177. Prior authorization is "[a]pproval from a health plan that may be required before [one gets] a service or fill[s] a prescription in order for the service or prescription to be covered by [a health] plan," *see* https://www.healthcare.gov/glossary/prior-authorization. Step therapy is a "type of prior authorization for drugs" that starts treatment with the most preferred therapeutic and only advances to other therapeutics if necessary, *see* https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs. Quantity limits are the maximum amount of a prescription drug that a pharmacy can dispense over a certain period that will be covered by a health plan, *see* https://www.caremark.com/portal/asset/Quantity_Limits_from_Fairfax_Drug_Lists_Guide.pdf.
[84] https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.119.044976; https://www2.deloitte.com/us/en/insights/industry/life-sciences/pharmaceutical-pricing-market-access.html.
[85] https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.119.044976
[86] Medicare Part D plans are required to cover drugs in six "protected" classes: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics. *See* https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit.
[87] https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.119.044976
[88] *See*, *e.g.*, Grabowski, Henry, Genia Long, Richard Mortimer, and Ani Boyo, "Updated trends in US brand-name and generic drug competition," *Journal of Medical Economics* vol. 19, 9 (2016): 836-44, Figure 5 (available at https://www.tandfonline.com/doi/epdf/10.1080/13696998.2016.1176578); Danzon, Patricia M., and Michael F. Furukawa, "Cross-National Evidence on Generic Pharmaceuticals: Pharmacy vs. Physician-Driven Markets," *NBER Working Paper* No. 17226 (2011), Figure 6 (available at https://www.nber.org/system/files/working_papers/w17226/w17226.pdf); Grabowski,

from branded drugs has increased in recent decades. For example, branded products' share of prescriptions for a molecule 12 months after generic entry was slightly below 50 percent for molecules that lost patent protection in 1999 and 2000, and just between 20 and 25 percent for those that lost patent protection between 2017 and 2019.[89] Driving these outcomes are physicians' and payers' price/cost considerations (which are generally tied to drug placement on insurance formularies) as well as pharmacy-level dynamics driven by generic substitution laws and pharmacies' financial incentives.

41. As noted above, the tiered cost structure of insurance formularies forms the basis for competitive dynamics with respect to pricing in pharmaceutical marketplaces, including (in particular) where generic products are available on the market. Because manufacturers of generic substitutes typically charge significantly lower prices than those charged by branded drug manufacturers, payers typically place branded drugs on less preferred formulary tiers than their generic equivalents. This is meant to discourage prescriptions for the branded drug – which is more expensive to the insurers – by now raising the cost of the branded drug to make it more expensive to the patient than the generic substitute. The diminished formulary coverage and disadvantaged pricing of the branded reference product commonly affect its sales relative to those of the generic product.

42. Additionally, the speed of generic penetration and the magnitude of the discount below brand price depend, to a significant extent, on the number of generics that enter the marketplace.[90] For example, a 2019 study evaluating median generic prices relative to brand price before generic entry

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Henry, Genia Long, Richard Mortimer, and Mehmet Bilginsoy, "Continuing Trends in U.S. Brand-name and Generic Price Competition," *Journal of Medical Economics*, 24:1, 908-917 (2021), Figure 5 (available at https://www.tandfonline.com/doi/pdf/10.1080/13696998.2021.1952795).

[89] *See* Grabowski, Henry, Genia Long, Richard Mortimer, and Mehmet Bilginsoy, "Continuing Trends in U.S. Brand-name and Generic Price Competition," *Journal of Medical Economics*, 24:1, 908-917 (2021), Figure 5 (available at https://www.tandfonline.com/doi/pdf/10.1080/13696998.2021.1952795). This trend was reported as early as 2004 (*see* Henry Grabowski, "Are the Economics of Pharmaceutical Research and Development Changing? Productivity, Patents and Political Pressures," *PharmacoEconomics*, 22:2, 15-24 (2004)).

[90] *See, e.g.*, Saha, Atanu, Henry Grabowski, Howard Birnbaum, Paul Greenberg, and Oded Bizan, "Generic competition in the US pharmaceutical industry," *International Journal of the Economics of Business* 13, no. 1 (2006): 15-38; Conrad, Ryan and Randall Lutter, "Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices," FDA (2019), p. 2 (available at https://www.fda.gov/media/133509/download).

showed that among drugs with initial generic entry from 2015 to 2017, generic drug prices and the generic-to-brand price ratio generally decreased with each additional generic producer.[91]

43. Regulations governing how branded and generic prescriptions are dispensed at pharmacies also favor use (and sales) of generic products. Once a generic substitute launches in the marketplace, it is significantly advantaged by pharmacy-level prescription dispensing regulations. As of 2019, every U.S. state had some form of generic substitution law that encourages pharmacies to fill prescriptions with the generic version of the prescribed drug.[92] Moreover, generic substitution is mandated by law in 19 U.S. states and territories.[93] I understand from counsel that these laws are indication-agnostic, allowing for substitution even where the prescription fill is intended for an indication or patient population not included on the generic labeling. Therefore, even if corresponding brand and generic products were priced at parity, regulations governing pharmacy-level practices provide a significant competitive advantage to the generic. Only when a prescribing physician actively marks a branded prescription with "dispense as written" or "brand medically necessary" must the pharmacy filling that prescription provide the branded drug instead of its generic substitute.[94]

44. In addition to the legal incentives favoring generic substitution, pharmacies are also financially incentivized to dispense generic medications. Research shows that "retail pharmacies profit more when dispensing generic versus branded drugs."[95] Payers also monetarily reward pharmacies for

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[91] Conrad, Ryan and Randall Lutter, "Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices," FDA (2019), p. 2 (available at https://www.fda.gov/media/133509/download). Previous research demonstrates similar results. For example, a 2011 study showed that relative to a marketplace with only one generic entrant, U.S. price-per-dose decreased approximately 47 percent with two or three generic entrants and 74 percent with four or more generic entrants. *See* Danzon, Patricia M., and Michael F. Furukawa, "Cross-National Evidence on Generic Pharmaceuticals: Pharmacy vs. Physician-Driven Markets," *NBER Working Paper* No. 17226 (2011), Table 3, pp. 16, 21 (available at https://www.nber.org/system/files/working_papers/w17226/w17226.pdf); ($0.47 - $0.88) / $0.88 = - 46.6%; ($0.23 - $0.88) / ($0.88) = -73.9%.

[92] Generic substitution is permitted by law in 31 out of the 50 states and in the District of Columbia. Generic substitution is mandated by law in an additional 19 states/territories. Sacks, Chana A., Victor L. Van de Wiele, and Lisa A. Fulchino, "Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions," *JAMA internal medicine* vol. 181(1) (2021): 16-22 (available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7489381).

[93] Sacks, Chana A., Victor L. Van de Wiele, and Lisa A. Fulchino, "Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions," *JAMA internal medicine* vol. 181(1) (2021): 16-22 (available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7489381).

[94] https://www.uspharmacist.com/article/generic-substitution-laws

[95] https://www.healthaffairs.org/do/10.1377/forefront.20170912.061887; https://www.insurance.wa.gov/sites/default/files/2017-06/pharmacy-supply-chain-study_0.pdf, p. 6.

dispensing generics.[96] In addition to the lower direct costs incurred by pharmacies themselves, generally increasing generic usage has provided payers with greater leverage to negotiate lower prices for generic products with their manufacturers (which in turn puts even greater downward pressure on corresponding branded prices).[97]

D. The '659 and '918 Patents and Nexus

45. Novartis's counsel informs me that U.S. Patent 8,101,659 ("the '659 patent"), asserted in the above-captioned 20-md-2930 action, covers a pharmaceutical composition comprising sacubitril or a pharmaceutically acceptable salt thereof, and valsartan or a pharmaceutically acceptable salt thereof. I understand the '659 patent, including its pediatric exclusivity, expires on July 15, 2025.

46. It is my understanding that the combination of sacubitril and valsartan, which is claimed in the '659 patent, are responsible for the therapeutic efficacy of Entresto® in the treatment of heart failure. Novartis's counsel also has informed me that MSN's generic products, like Entresto®, include the combination of sacubitril and valsartan as their active ingredients. I understand the combination of sacubitril and valsartan claimed in the '659 patent is responsible for the therapeutic efficacy of MSN's generic products, (as is the case with Entresto®), and as such, I understand there is a nexus between the claimed features of the '659 patent and the prospective demand for the MSN's generic sacubitril/valsartan products. I further understand from counsel that MSN's generic products contain an amorphous trisodium sacubitril-valsartan complex, as claimed in U.S. Patent No. 11,096,918 ("the '918 patent"), and as such, I understand there is also a nexus between the claimed features of the '918 patent and MSN's generic products.

III. IRREPARABLE HARM ASSESSMENT

47. In this section, in light of the background set forth above, I assess whether Novartis would suffer material and irreparable harm were MSN to launch its generic sacubitril/valsartan products "at risk" and subsequently be required to withdraw the products from the marketplace. In this context, I understand that irreparable harm is economic harm resulting from generic entry for which subsequent monetary compensation or permanent injunctive relief would be inadequate to fully compensate the patentee.

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[96] https://www.healthaffairs.org/do/10.1377/forefront.20170912.061887
[97] https://www.healthaffairs.org/do/10.1377/forefront.20170912.061887

48. As discussed in Section I.B, I understand MSN may launch its generic sacubitril/valsartan products "at risk" in view of the District Court's July 2023 decision invalidating the '659 patent and the July 2024 FDA approval of MSN's products; that such a launch may trigger the launch by multiple Defendants (or other generic manufacturers) of their generic sacubitril/valsartan products; and that such products would remain on the market for several months until they are withdrawn pursuant to a subsequent injunction. I have been further asked to assume that, should a subsequent injunction issue, generic versions of Entresto® will not be permitted in the U.S. until at least July 2025, and potentially later.

49. In my assessment of possible irreparable harm, I consider multiple forms of potential harm. First, I consider the impact of "at-risk" generic entry on Novartis's sales and profits generated by sales of Entresto®. I find that not only will such harm likely be of substantial magnitude, but also that such harms would likely be irreparable for multiple reasons. For one, full and reliable quantification of such harm – as would be required at a subsequent trial as a prerequisite to compensating Novartis for such harm – would be incredibly difficult. Furthermore, even if such a quantification were attempted, it is not evident that MSN would be in a financial position to pay such a judgment. I next consider secondary harms to Novartis driven by lingering impacts on Entresto® effective net pricing and impacts from Novartis's accelerated reductions in Entresto® investment. Ultimately, I conclude that Novartis stands to be irreparably harmed by the premature and at-risk entry of MSN.

A. Direct Impact of Generic Competition on Entresto® During At-Risk Launch Period

50. Given the dynamics of generic entry in the pharmaceutical industry discussed above in Section II.C, generic entrants typically harm the reference branded product competitively in two primary ways. First, various mechanisms – including generic substitution laws and financial incentives for pharmacies to dispense generics in lieu of the branded reference product[98] – result in substantial and immediate substitution of prescription volumes from the reference brand to the generic

[98] Pharmacists' dollar margins on generic prescriptions (particularly newly introduced generics) tend to be higher than on branded products. For example, a 2010 study by the U.S. Department of Health and Human Services states that "[p]harmacies typically have higher markups for new generic drugs than branded drugs and older generic drugs." U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE), Issue Brief, "Expanding the Use of Generic Drugs," December 1, 2010, p. 5 (available at https://aspe.hhs.gov/system/files/pdf/76151/ib.pdf). *See also,* F.M. Scherer, "The Pharmaceutical Industry — Prices and Progress," *The New England Journal of Medicine*, 351:9 (2004): 927-932, p. 930 (available at https://www.nejm.org/doi/full/10.1056/nejmhpr040117).

alternatives. Second, price competition from generic entrants typically leads payers/PBMs to place the generic products in advantaged formulary positions relative to the reference brand (including, commonly, dropping the brand from formulary altogether), leading to additional generic substitution as physicians and patients elect to write and fill prescriptions for generics, given their relatively lower copays. To the extent a brand attempts to engage in price competition with the generic entrants by, for example, offering additional rebates to payers in hopes of retaining its preferred formulary positions, this can also lead to significant price erosion sustained by the brand on its retained volumes. Though there is considerable variation in observed outcomes in generic entry scenarios, these dynamics often cause steep and immediate losses in sales volumes for branded products, which are commonly paired with price erosion sustained on the brand's retained sales.[99]

51. In this context, if Novartis were to face entry by MSN (and potential follow-on entrants), it could select a competitive response along a spectrum [redacted]. On one end of the spectrum, [redacted]. On the other end, [redacted]. However, [redacted], which would be difficult or impossible to fully reverse if the generic entrant(s) later withdrew from the marketplace.

52. In the present case, I understand that Novartis's likely competitive response to generic entry would likely depend on the number of generic entrants and other characteristics of the at-risk launch.[100] In the remainder of this section, I first assess the likely harms associated with each of these potential generic entry scenarios, and then I discuss the irreparable elements of such harm.

[99] *See* Section II.C.2.
[100] Conversation with Kristin Miller. Conversation with Robert Rubinsky and Daniel DiMeo.

1. Substantial Impact of Generic Entry

a. Single-Entrant Scenario

53. I understand from Kristin Miller, Novartis Vice President and General Manager – Pelacarsen and Heart Failure, that if faced with a single generic entrant, Novartis would have to consider its options in light of the aggressiveness of the entrant's launch, and the nature of the generic entrant itself. Among other options, I understand that Novartis would consider [redacted] In such situations, the brand is still harmed in two immediate ways. First, to the extent the brand provides [redacted] Second, even assuming the brand employs [redacted] Given the magnitude of Entresto® U.S. net sales (which, as discussed further below, are expected to exceed [redacted] billion in 2024 alone), these harms to Novartis will no doubt be substantial irrespective of the ultimate pricing levels for the generic entrant and the brand.

54. Leaving aside the particulars of the extent to which Novartis may employ a [redacted] strategy upon generic entry, I understand that internal Novartis forecasting has estimated that within the first month after a single generic launch, assumed to occur in mid-2024, branded Entresto® would lose [redacted] of forecasted new-to-brand ("NBRx") prescriptions and [redacted] of total prescriptions ("TRx").[103] The faster forecasted decline in new-to-brand prescriptions, which is generally a leading directional indicator of total prescriptions, implies that Novartis expects payers to begin switching patients off the brand almost immediately upon generic entry. Further, in this scenario, within the first six months after a single generic launch, Novartis forecasted that branded Entresto® would lose nearly [redacted] of new-to-brand prescription volume and nearly [redacted] of total prescriptions – consistent with the brand erosion curves observed in the academic literature

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[101] Conversation with Kristin Miller.
[102] Additionally, I understand that [redacted] Conversation with Robert Rubinsky and Daniel DiMeo.
[103] Ex. 4, ENT_2024 Impact Single Generic.xlsx. [redacted]

discussed above.[104] Unsurprisingly, given the more than $[redacted] in U.S. net sales Novartis expects Entresto® to generate in 2024, these volume losses would translate into enormous dollar impacts.[105] Indeed, Novartis expects that the combination of its loss in branded Entresto® prescription volume, plus the impact on effective Entresto® pricing, would reduce forecasted net sales by hundreds of millions of dollars over several months following generic entry.[106] This does not include any residual pricing or prescription volume impacts that could carry through 2025 even if Novartis regained branded exclusivity in 2025.

b. Multiple Entrants Scenario

55. As under a single-entrant scenario, I understand Novartis's strategic response to multiple generic entrants would depend on the nature of, and the participants in, the at-risk launch.[107] However, at a theoretical level, the adverse impact of multiple generic entrants on the brand – be it via pricing pressure or displacement of sales volumes – is commonly greater than the impact of a single-entrant generic launch on the brand.[108] Consistent with this expectation, I understand that internal Novartis forecasting has estimated that within the first month of generic entry with multiple entrants, branded Entresto® would lose [redacted] of forecasted new-to-brand prescriptions and [redacted] of total prescriptions.[109] As I mentioned in the previous scenario, the faster forecasted decline in new-to-brand prescriptions, which is generally a leading directional indicator of total prescriptions, implies that Novartis expects payers to begin switching patients off the brand almost immediately upon generic entry. Further, within the first six months of generic entry, Novartis forecasted branded Entresto® would lose approximately [redacted] of prescription volume for both new-to-brand and total prescriptions – consistent with the upper end of brand erosion curves observed in the academic literature discussed above.[110]

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[104] Ex. 4, ENT_2024 Impact Single Generic.xlsx. [redacted]. *See also* Section II.C.2.
[105] Ex. 4, ENT_2024 Impact Single Generic.xlsx. Additionally, I note that these dollar losses are based on a forecast of Entresto® generating more than [redacted] in U.S. net sales, which Entresto® seems poised to surpass. *See* Ex. 13 and Section III.A.2.a below.
[106] Ex. 4, ENT_2024 Impact Single Generic.xlsx
[107] Conversation with Kristin Miller.
[108] *See* Section II.C.2.
[109] Ex. 3, ENT_2024 Impact.xlsx.
[110] Ex. 3, ENT_2024 Impact.xlsx. [redacted] *See also* Section II.C.2.

56. Unsurprisingly, given the more than [redacted] billion in U.S. net sales Novartis expects Entresto® to generate in 2024, these volume losses – combined with pricing effects – would translate into enormous dollar impacts.[111] Indeed, Novartis expects that the combination of its loss in branded Entresto® prescription volume, plus the impact on effective Entresto® pricing, would reduce forecasted net sales by substantially more than in the single-entrant scenario discussed above.[112] Further, as was the case in the single-entrant scenario, these forecasted losses do not include any residual pricing or prescription volume impacts that could carry through 2025 even if Novartis regained branded exclusivity in 2025.

2. Irreparable Elements of Such Harm

57. As laid out in the previous subsection, an illustrative calculation of the harm to Novartis's branded Entresto® sales and profitability driven by either a single or multiple generic entrants in 2024 – even for the period limited to several months in late 2024 – ranges from the mid-to-high hundreds of millions of dollars in lost net revenues. However, harm of this magnitude, which is only a subset of the full set and magnitude of harm to Novartis discussed throughout this section, is irreparable for at least two reasons. I discuss those reasons presently.

a. Difficulty in Forecasting "But-For" Revenues

58. As an initial matter, I understand that in order to compensate a patentee for harm stemming from patent infringement, it must be possible to compute damages fully and to a reasonable degree of economic certainty. In the present case, such a damages computation, assuming an at-risk generic entry had occurred, would require the estimation of Novartis's revenues and profits generated by Entresto® sales in a world "but for" said generic entry. With such an estimate in hand, a damages expert could compare Novartis's "but for" profits with those it generated in the actual world (information that would presumably be available on a historical basis at a future trial) to derive an estimate of Novartis's "lost profits" for the limited time period of the pendency of the at-risk launch and corresponding to Entresto® sales only – which, as I discuss throughout this declaration, are not the only harms Novartis stands to sustain should one or more generics launch their products. However, I find that even Novartis's own forward-looking forecasts of

[111] Ex. 3, ENT_2024 Impact.xlsx
[112] Ex. 3, ENT_2024 Impact.xlsx

Entresto®'s net revenues are likely to understate a complete and reliable measure of Entresto®'s "but-for" net revenues.

59. To assess the reliability of Novartis's internal forecasting, I reviewed the information available to me relating to Novartis's prior forecasts for Entresto®. I observe that in recent years, Novartis has consistently revised its forecasts for future Entresto® sales significantly upward. Notably, despite this consistent trend of upward revisions, I observe that Novartis's estimates of Entresto®'s annual U.S. net revenues have nonetheless continued to significantly underestimate Entresto®'s actual net performance. I demonstrate this dynamic in Figure 2, which depicts Novartis's various forecasts of total Entresto® U.S. net revenues for each year, and where, moving from left to right, the successive forecasts (and, ultimately, the actual net sales) are reported. As shown, in its typical three-year forecasts, Novartis has consistently under-forecasted Entresto® net sales, even for the most immediate year in the forecast period.

Figure 2: Novartis Entresto® Forecasted and Actual U.S. Net Sales ($ millions)

Source: Exhibit 13

60. This trend of under-forecasting has continued into 2024, with Entresto®'s $1,895 million of actual U.S. net revenues in the first half of 2024 already exceeding Novartis's most recent forecast ("2024 1FP") for the same period by nearly [redacted], strongly suggesting that Entresto®'s 2024 full year net sales will materially exceed even Novartis's most recent heightened forecasts.[113] Entresto®'s H1 2024 overperformance comes on the heels of Novartis increasing their 2024 1FP forecast of Entresto®'s 2024 full year net sales by [redacted] relative to their 2023 1FP forecast of 2024 net sales.[114] Additionally, Novartis's 2024 1FP forecast included an upward revision of Entresto®'s 2025 full year net sales by [redacted] over the 2023 1FP forecast values, larger than previous forecast updates and further demonstrating Entresto®'s sustained overperformance.[115]

61. To better understand Novartis's perspective on these dynamics, I discussed them with Kristin Miller. She explained that Entresto® has consistently exceeded forecasts in recent years as physicians have shifted to prescribing Entresto®, as opposed to ACEis and ARBs, to HFrEF patients. She further explained that this shift has come in response to recent clinical trials and updated clinical guidelines that more strongly recommend Entresto®.[116] I further understand these trends are likely to continue as prescriber awareness of updated expert consensus decision pathways (most recently published for HFrEF patients in 2024 and HFpEF patients in 2023, as discussed previously in Section II.B.2) increases. Additionally, I understand from Kristin Miller that further guideline and treatment updates for HFpEF patients could be issued at any time, and stronger guideline recommendations for Entresto® among this subset of patients could materially impact future demand.[117]

62. Returning to a potential backward-looking damages computation, the high likelihood that Novartis's existing forward-looking forecasts for Entresto® net revenues actually *understate* Novartis's but-for net revenues means that any lost profits computation based on them would similarly understate Novartis's lost profits – even for the component of harm to Novartis based

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[113] Ex. 3, ENT_2024 Impact.xlsx, where Q1 2024 actual Entresto® U.S. net sales are, in millions, ($362 + $314 + $272) = $948 and H1 2024 forecasted Entresto® sales are, in millions, [redacted]; https://www.novartis.com/sites/novartis_com/files/2024-07-interim-financial-report-en.pdf, p. 37, where Q2 2024 actual Entresto® U.S. net sales are $947 million. Thus, [redacted]. Additionally, [redacted]

[114] Exhibit 13, where, in millions, [redacted]

[115] Exhibit 6, where, in millions, [redacted]

[116] As discussed in Section II.B.2. Conversation with Kristin Miller.

[117] Conversation with Kristin Miller.

solely on lost Entresto® sales (or price erosion on retained Entresto® sales) during the pendency of any at-risk launch. If Novartis were unable to be fully compensated because a full and reliable computation of its lost profits damages cannot be performed, such harm is irreparable from an economic perspective.

b. MSN's Inability to Pay a Potential Judgment

63. In the previous subsection, I detailed why it would be extremely difficult to generate a full and reliable quantification of the damages to Novartis stemming from its revenue and profit losses on branded Entresto® even during the period limited to the pendency of any at-risk launch. Here, I explain that even using the illustrative lost profits estimates based on prevailing Novartis forecasts – which would likely fail to fully compensate Novartis for its lost profits due to MSN's infringement, but is instructive as to the order of magnitude of such damages – MSN would be unlikely to be able to pay such a damages judgment based on public information about its financial position.

64. First, I conduct an illustrative computation of potential damages exposure using Novartis's internal forecasting of the impact of a 2024 generic entry (as referenced in Section III.A.1, above). I also limit my analysis of the adverse impact to Novartis to the window of September 2024 through December 2024, the approximate time period during which I have been asked to assume MSN's sacubitril/valsartan generic (and, potentially, those of other follow-on generic entrants) would be available on the market before facing a potential permanent injunction based on the timeline associated with the '659 patent appeal process.[118] As noted, this exercise does not account for any additional damages or lost sales that Novartis is likely to suffer even after the withdrawal of MSN's and any other entrants' generic products from the market. It also does not account for the other forms of harm Novartis is likely to sustain due to generic entry, nor does it adjust for the fact that Entresto®'s net revenues thus far in 2024 have already exceeded the 2024 forecasts on which these estimates are based.[119] Finally, to the extent the pendency of the at-risk launch were assumed to span September 2024 through May 2025 (as would be the case based on the timeline

[118] The Novartis Erosion Curves available to me show the impact on Entresto® prescriptions of a generic launch taking place in [redacted]. However, as mentioned previously, I have been asked by counsel to assume that MSN will launch at risk on August 27, 2024. I therefore calculate an erosion curve for Entresto® net sales and apply this erosion curve starting in September 2024. *See* Exhibit 14.

[119] *See* Sections III.B.1 and III.A.2.a.

associated with the '918 patent district court litigation), any harms considered here would, *a fortiori*, be of an even greater magnitude.

65. In Exhibit 14, I display forecasted illustrative potential damages exposure under two scenarios, one where MSN is the only at-risk generic entrant, and one where MSN's launch triggers additional generic competitors to launch their own products. Using Novartis's forecasts of single- and multiple-entrant scenarios, Entresto®'s net revenues from January 2024 to December 2024 would fall from approximately [redacted] billion to approximately [redacted] in the single-entrant scenario or to approximately [redacted] under a multiple-entrant scenario.[120] This illustrative exercise implies that Entresto® stands to lose net revenues on the order of at least [redacted] million in just the final 4 months of 2024 if there were an at-risk launch by MSN and/or additional generic entrants.[121] To arrive at an approximate impact on profits, I apply Novartis's prevailing incremental margin for Entresto®, which I estimate to be [redacted]%.[122] This yields an illustrative damages estimate on the order of [redacted] in just the final 4 months of 2024 if there were a launch by MSN and/or additional generic entrants.[123]

66. Next, I consider MSN's ability to pay an amount on this order of magnitude. I recognize that by virtue of its at-risk launch, MSN may have available to it any profits gained from its infringing net sales, profits which it could direct towards such a payment. I also recognize that if MSN were to launch "at risk" its generic sacubitril/valsartan products, it would likely do so at a steep net price discount to that of branded Entresto®. Thus, to the extent that MSN's generic products simply displace prescriptions of Entresto®, MSN stands to gain significantly less than Novartis stands to lose, as MSN's profits for its generic products (on a dollars per-unit basis) would be lower than the per-unit profit lost by Novartis.[124] Furthermore, if MSN's entry triggers a "jailbreak" scenario where additional generics also enter the marketplace, then the sales captured by MSN would

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[120] Exhibit 14.
[121] Exhibit 14.
[122] Calculated as Novartis's March 2024 year-to-date operating margin based on Ex. 2, Entresto 2020 - 2024 March HC.xlsx (worksheet '2024') and my understanding from my conversation with Ashley Reid and Amogh Purandare that Entresto®'s effective gross margin is approximately [redacted]%. I understand that the COGS in Ex. 2 reflect [redacted]. Thus, I calculate Entresto®'s operating margin as [redacted].
[123] Exhibit 14.
[124] As discussed in Section II.C.2, this dynamic is expected given standard economic models of competition, which predict that total producer surplus falls as more firms enter. In other words, the total available profits earned by firms falls as the number of firms competing increases.

represent only a portion of the sales losses that Novartis will incur.[125] In Exhibit 14, I provide an estimate of the net sales that will accrue to MSN in both single- and multiple-entrant scenarios. Assuming that MSN would generate 20% less net revenue per prescription than Novartis during the same period, I estimate that MSN's net sales during the at-risk launch period associated with the '659 patent would range from [redacted] million, if it were the only generic entrant, to [redacted] million, assuming multiple entrants.[126] Applying an incremental margin similar to the one I used for Novartis, I estimate MSN would generate [redacted] to [redacted] million in incremental profit during this period.

67. Furthermore, I recognize that MSN would be able to use the profits derived from the sale of its other approved products, conservatively assuming they would not be needed for other purposes. I understand MSN has not produced financial information in this case; however, it does report on its homepage that it generated $750 million in revenue in 2023.[127] Assuming that MSN's consolidated profit margins are similar to those disclosed by other generic pharmaceutical manufacturers, MSN's $750 million in annual revenue would likely translate to between $113 and $171 million in annual net profit before tax or approximately $151 to $239 million in annual earnings before interest, taxes, depreciation, and amortization ("EBITDA").[128] Taking the entirety of MSN's annual profit derived from other products combined with the incremental profits generated by its infringing sales during the at-risk launch period, this exercise implies that MSN

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[125] Additionally, to the extent that the presence of a generic product available compels [redacted]. I note that [redacted]. See Exhibit 14.

[126] Historical retail pharmacy pricing data suggests that in scenarios where only one manufacturer launches a generic competitor to a branded drug that has experienced loss of exclusivity, that lone generic manufacturer's price is between roughly 70 to 85 percent of the branded drug's post-generic entry price. *See, e.g.*, Aitken, Murray L., Ernst R. Berndt, Barry Bosworth, Iain M. Cockburn, Richard Frank, Michael Kleinrock, Bradley T. Shapiro. "The Regulation of Prescription Drug Competition and Market Responses: Patterns in Prices and Sales Following Loss of Exclusivity," Measuring and Modeling Health Care Costs (2018) (available at https://www.nber.org/system/files/chapters/c13094/c13094.pdf, pp. 18-19). I understand from my conversation with Ashley Reid and Amogh Purandare that Novartis's multiple-entrant forecast scenario assumes there are [redacted] generic entrants. I assume under a multiple-entrant scenario that MSN would capture one-third of the generic prescription share.

[127] https://www.msnlabs.com/our-achievements.html

[128] Exhibit 15. Note these estimates are consistent with additional studies that show net profit margins for generic pharmaceutical manufacturers range from 13% to 20%, and have been declining over time. Sood, Neeraj, et al. "The Flow of Money Through the Pharmaceutical Distribution System" USC Schaeffer Center White Paper Series (2017) (available at https://healthpolicy.usc.edu/wp-content/uploads/2017/06/The-Flow-of-Money-Through-the-Pharmaceutical-Distribution-System_Final_Spreadsheet.pdf, Table 2.) and https://kpmg.com/kpmg-us/content/dam/kpmg/pdf/2023/generics-2030.pdf, p. 7.

would likely have, at most, $188 to $388 million in profits to compensate Novartis for, at least, [redacted] to [redacted] in damages.[129] As such, Novartis's likelihood of being fully compensated by MSN for this illustrative impact on Entresto® profits appears exceedingly low, since, as discussed above, this illustrative exercise provides only a likely lower bound to the damages Novartis will sustain. Indeed, this exercise does not account for the fact that Entresto®'s actual H1 2024 net sales have thus far exceeded Novartis's forecasts, nor does it reflect the various additional harms Novartis stands to suffer, which I discuss in the following subsection.

B. Additional Harms

68. Beyond the substantial and irreparable harms stemming from Novartis's loss of revenues and profits from Entresto® sales during the pendency of a 2024 at-risk launch, Novartis stands to be harmed in additional ways. Here, I discuss the ongoing harms to the Entresto® franchise that would likely last beyond MSN or any follow-on entrants' withdrawal of their generic products, as well as the indirect harm to Novartis's related product lines.

1. Continuing Harm to Entresto® Following Generic Withdrawal

69. Assuming a 2024 generic entry were followed by a subsequent withdrawal in December 2024, Entresto®'s profitability stands to continue to be impacted in ways not captured by the illustrative analyses discussed above. First, following a generic launch and exit, Novartis would be extremely unlikely to be able to fully restore its pre-generic effective net pricing. Large payers, including private insurers, often refuse to agree to significant price increases and would likely resist Novartis's efforts to restore Entresto®'s effective price to the level it was at before the improper generic entry.[130] Indeed, I understand a request to raise prices back to prior levels may strain

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[129] *See* Exhibit 15, where the minimum net profit after tax among comparator companies to MSN is $113 million and the maximum EBITDA among comparator companies is $239 million. *See also*, Exhibit 14, where the minimum net profit on a sacubitril/valsartan generic (in a single entrant scenario) for MSN is illustratively estimated at $75 million and the maximum net profit is illustratively estimated at $149 million. Adding the respective minimums and maximums together, in millions: ($113 + $75) = $188 and ($239 + $149) = $388.

[130] Conversation with Kristin Miller; Conversation with Robert Rubinsky and Daniel DiMeo. I further understand that even had Novartis [redacted], it would be extremely difficult for Novartis [redacted]. In particular, I understand Novartis expects that, given the highly competitive payer contracting environment for heart failure treatments, and the emergence of SGLT2is, at least some payers would attempt to extract pricing concessions from Novartis once any generic entrants had withdrawn. Indeed, I understand that many Novartis contracts with payers [redacted]. In a scenario where there are multiple generic entrants that are subsequently withdrawn, Novartis would have to [redacted]

Novartis's relationships with certain payers.[131] Additionally, Novartis may have to make concessions to some payers to restore Entresto®'s pre-generic formulary coverage and to avoid payers adding barriers such as prior authorizations[132] or step therapy requirements[133] to Entresto®.[134] Thus, at least some components of Novartis's price erosion sustained on retained sales volumes would likely persist even after Entresto® regained its branded exclusivity following generic withdrawal. Estimating damages associated with such harms would likely be even more difficult than the exercise described above, since it would require reliable estimates of Novartis pricing, revenues, and profits further into the future.

70. Second, I understand from Kristin Miller that the significant loss of revenues that would come with early generic entry (relative to the mid-2025 or later generic entry I understand Novartis expects but for an imminent at-risk launch), which fund Novartis' ongoing investments in the Entresto® brand, including investments in the Entresto® sales force and its patient support programs, could thus force Novartis to accelerate its plans to scale down those programs.[135] Any such acceleration would likely temper the current marketplace momentum of sacubitril/valsartan treatment generally, not only during the pendency of an at-risk launch by one or more generic entrants, but thereafter as well.

71. As detailed in Section II.B.3 above, sacubitril/valsartan treatment (via branded Entresto®) has enjoyed strong and steady marketplace momentum in recent years. This momentum has accumulated as Entresto® has received growing recognition from treatment guidelines – e.g., the recognition in the AHA/ACC/HFSA guideline of Entresto®'s superiority in treating HFrEF (relative to ACEis)[136] – and increased trial and usage by prescribing physicians. I understand Novartis's ongoing efforts to

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[131] Conversation with Robert Rubinsky and Daniel DiMeo.

[132] Prior authorization ("PA") requires physicians to submit a form regarding the potential use of a regimen for treatment to the insurer for review, based on which the insurer will then either approve or deny the requested regimen. Some PAs also come with a requirement for physicians to provide various pieces of information (e.g., genetic tests or other therapeutical statistics as listed in the drug label) before the approval is granted. *See* https://info.mmitnetwork.com/hubfs/Payer%20Strategies%20Across%20Pharmacy%20and%20Medical%20Benefits%20-%20MMIT-1.pdf, pp. 2-3.

[133] Step therapy requires that a specific drug be tried before another, more expensive drug will be covered. Step therapy can also be placed within prior authorization criteria sets. *See* https://www.shrm.org/resourcesandtools/hr-topics/benefits/documents/understanding_specialty_pharmacy_management_and_cost_control_final.pdf, p. 11.

[134] Conversation with Robert Rubinsky and Daniel DiMeo.

[135] Conversation with Kristin Miller.

[136] For example, Entresto®'s label reports the results of the PARADIGM-HF clinical trial, demonstrating Entresto®'s superiority compared to enalapril, an ACEi. *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/207620s018lbl.pdf, pp. 5, 13. *See also* Section II.B.2.

continue to educate physicians about such guidelines and Entresto®'s therapeutic profile have contributed to this continuing marketplace momentum.[137] Indeed, Novartis business planning documents have identified significant cohorts of '[redacted].[139] To support physician education efforts, I understand Novartis employs a considerable cardiovascular sales force, including teams of hundreds of sales professionals who support Entresto® in some capacity, with many also focusing on Leqvio® (another drug in Novartis's cardiovascular portfolio).[140] I further understand Novartis provides a variety of patient support programs and initiatives to increase patient access to Entresto®, improve awareness of heart failure more generally, and support patient adherence for those taking Entresto®.[141]

72. However, in the face of generic entry, I understand Novartis may accelerate its planned reductions of these ongoing investments in the Entresto® brand.[142] Notably, generic entrants would be unlikely to replace any decrease in Novartis investments in patient and prescriber education, depriving the entire space (i.e., branded Entresto® and any generic version thereof) of a primary growth driver. At a high level, the business model of generic drug manufacturers is to rely entirely on brand manufacturers' promotional and research and development efforts, and to compete strictly on price.[143] Moreover, the entry of any generic supplier reduces the incentive for *any* supplier, including the branded supplier, to invest in growing the treatment patient population.[144]

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[137] Conversation with Kristin Miller.
[138] Ex. 1, 2023 Prioritizing Entresto's Marketing Strategy_11_11_22 pre-read.pdf, p. 8.
[139] Ex. 10, NPC-VS-016683138 at 142, noting that Novartis estimates [redacted]
[140] Conversation with Kristin Miller.
[141] These programs and initiatives include a call center with patient support specialists, co-pay assistance, and a 12-month patient lifecycle program to support patient adherence. Conversation with Kristin Miller. Novartis reported estimated costs of approximately [redacted] million associated with its patient assistance programs in 2023 alone, *see* Ex. 2, Entresto 2020 - 2024 March HC.xlsx.
[142] I understand from my conversation with Kristin Miller that the pace of these changes may be slightly slower in the case of a single generic entrant, but that these program ramp downs would still occur in a matter of months after a generic launch.
[143] Grabowski, Henry., et al. "Does Generic Entry Always Increase Consumer Welfare?" *Food and Drug Law Journal* (2012) (available at https://pubmed.ncbi.nlm.nih.gov/24624656).
[144] One study found that across 35 different drugs with generic entrants that the combined total branded and generic drug use decreased by 20 percent in the two years after generic entry. Huckfeldt, Peter J., and Christopher R. Knittel,

73. Accelerated reduction of these multi-pronged education efforts by Novartis to continue to expand the patient base for Entresto® – and the limited incentive for one or more generic entrants to replicate those efforts – will likely reduce the incremental patients that may have been treated with sacubitril/valsartan throughout 2024 and into 2025 had no generic entrants launched at risk. For example:

- With reduced ongoing outreach to clinicians, some cardiologists and primary care providers ("PCPs") who treat heart failure patients with ACEis and ARBs (even though the guideline specifies they should be on Entresto®) will likely continue to do so;[145]
- Novartis will be unable to take full advantage of educating physicians (and patients) about the recent results of its PARAGLIDE-HF clinical trial,[146] which I understand support the value of Entresto® treatment in HFpEF patients;[147]
- Novartis's reduced "share of voice" in physician-facing (and consumer-facing) promotion will open the door for SGLT2is to make further inroads (pulling from the same set of patients [redacted][148]);
- In the coming months, marketplace presence is expected to be particularly important for Novartis in the HFpEF marketplace, which I understand currently constitutes just a relatively modest minority of Entresto® prescriptions;[149]
- Any reduction in patient support programs for existing Entresto® patients (or prospective generic sacubitril/valsartan patients) could reduce patient persistence, leading to fewer patients on sacubitril/valsartan treatment overall.[150]

74. The aggregate sales volume losses across branded and generic sacubitril/valsartan treatments associated with these patient populations are unlikely ever to be recovered, even if generic any at-

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"Pharmaceutical Use Following Generic Entry: Paying Less and Buying Less," NBER Working Paper Series: (2011) (available at https://www.nber.org/papers/w17046).

[145] *See, e.g.*, Ex. 11, ENTRESTO Annual IPS Review_FINAL for Review 9.13.23.pptx (noting the Entresto® strategy to expand [redacted]).

[146] https://www.jacc.org/doi/10.1016/j.jacc.2023.04.019. *See also,* https://www.sciencedirect.com/science/article/pii/S1071916423000404.

[147] https://www.tctmd.com/news/more-arni-insights-fortify-role-below-normal-lvef-paraglide-hf. *See also*, https://www.jacc.org/doi/10.1016/j.jacc.2023.04.019; https://academic.oup.com/eurheartj/advance-article/doi/10.1093/eurheartj/ehad344/7173308.

[148] *See, e.g.*, https://www.tctmd.com/news/more-arni-insights-fortify-role-below-normal-lvef-paraglide-hf; Ex. 11, ENTRESTO Annual IPS Review_FINAL for Review 9.13.23.pptx.

[149] Conversation with Kristin Miller.

[150] *See, e.g.*, Ex. 10, NPC-VS-016683138 at 228; Ex. 9, NPC-VS-016672420 at 444 (noting that Product & Service solutions [redacted]).

risk generic entrants were subsequently withdrawn from the marketplace.[151] For example, incremental patients who may have switched to branded Entresto® during the remainder of 2024 in part because of Novartis's ongoing investments may instead continue on their current regimen indefinitely. Furthermore, I understand Novartis would face difficult decisions about resuscitating its reduced investments, even if any generic entrants subsequently withdrew their products (given the proximity to expected loss of branded exclusivity as soon as mid-2025). Quantifying these incremental impacts on the Entresto® brand during the 2024-2025 timeframe would be extremely difficult. As a result, these harms constitute additional irreparable harms Novartis would be likely to sustain were one or more entrants to launch a generic version of Entresto® in the absence of a preliminary injunction against MSN.

2. Non-Compensable Harms to Other Product Lines

75. Beyond the harms to Entresto® discussed above, generic entry would likely disrupt Novartis's efforts to sell its two other current and future principal products in the cardiovascular treatment field, Leqvio®, an FDA-approved cholesterol-lowering drug,[152] and pelacarsen, a drug currently in development to reduce lipoprotein(a).[153] I understand that Entresto®, Leqvio®, and the forthcoming pelacarsen share prescribers and have an overlap in targeted patients.[154] As such, Novartis currently uses (and would continue to use) the same sales force to support these medications.[155] The accelerated reduction to Entresto® sales force personnel and resources would thus likely translate into adverse impacts for Leqvio® at a relatively early stage of its lifecycle (and impact the period leading up to pelacarsen's potential launch), disrupting future sales growth trajectories in ways that are difficult to quantify.[156]

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[151] Since these negative impacts would impact the sales of both branded and generic sacubitril/valsartan treatments, any measure of lost sales that only accounts for Novartis sales lost via substitution to a generic would fail to account for the additional sales lost because of the harm done to patient and provider perceptions and awareness of these treatments generally.
[152] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/214012Orig1s000ltr.pdf
[153] https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf, p. 27. *See also*, https://www.novartis.com/news/media-releases/novartis-pursue-transformational-therapy-reduce-risk-cardiovascular-disease-people-living-elevated-levels-inherited-lipoproteina.
[154] Conversation with Kristin Miller.
[155] Conversation with Kristin Miller.
[156] I understand that the volume losses associated with the slowed growth of Leqvio® and pelacarsen in these scenarios would not be recoverable in a damages context.

76. But for early at-risk generic entry, I understand that Novartis would have significant additional flexibility to profitably redeploy or restructure the personnel and resources currently supporting Entresto® towards other products upon loss of Entresto®'s branded exclusivity. Specifically, given that Novartis has planned for a scenario in which Entresto® is expected to lose exclusivity in 2025, I understand that Novartis would consider shifting its personnel and resources either further towards Leqvio®[157] or towards pelacarsen.[158] "At-risk" generic entry thus disrupts Novartis's transition plans for Entresto® personnel and resources. Additionally, without the ability to redeploy existing Entresto® employees, Novartis would likely need to undertake additional efforts and incur additional costs to hire and train new employees to support pelacarsen if and when it launches.[159]

77. The harms that MSN's "at-risk" generic entry will impose on Novartis's other products, namely Leqvio® and pelacarsen, will be extremely difficult to quantify to a reasonable degree of economic certainty.

IV. CONSIDERATION OF BALANCE OF HARDSHIPS

78. In this section, I consider the balance of hardships relating to the issuance (or not) of an injunction that prevents the sale of MSN's generic products. I find that the hardships experienced by Novartis, in the absence of an injunction, will be significantly greater than the hardships experienced by MSN, if its "at-risk" generic sacubitril/valsartan products are enjoined from sale.

79. As discussed above, to the extent that the launch of a generic product simply displaced prescriptions of Entresto®, MSN stands to gain significantly less than Novartis stands to lose – since MSN's profits for its generic products (on a dollars per-unit basis) would typically be lower

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[157] Leqvio® is currently early within its product launch cycle and is expected to grow significantly in the next several years. As of 2023, Leqvio® has seen rapid growth and the continuation of this growth would reasonably allow for the absorption of higher numbers of sales representatives in 2025 than would be possible in 2024. From Novartis quarterly investor presentations, Leqvio®'s 2023 growth rate is approximately 217%, where its 2023 worldwide net sales were, in millions, ($64 + $78 + $90 + $123) = $355 and its 2022 worldwide net sales were, in millions, ($14 + $22 + $34 + $42) = $112, giving a growth rate of $355 – $112 / $112 = 216.96%. Leqvio®'s 2023 U.S. net sales of $205 million were 7% of Entresto®'s 2023 U.S. net sales of $3.1 billion. *See* https://www.novartis.com/sites/novartis_com/files/q1-2023-investor-presentation.pdf, p. 17; https://www.novartis.com/sites/novartis_com/files/q3-2023-investor-presentation.pdf, p. 14; https://www.novartis.com/sites/novartis_com/files/q4-2023-investor-presentation.pdf, p. 14; https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf, p. F-19; https://www.globaldata.com/media/pharma/novartis-leqvio-potential-lead-cholesterol-lowering-space-due-administration-convenience-says-globaldata/.

[158] Conversation with Kristin Miller.

[159] Conversation with Kristin Miller.

than the per-unit profit lost by the brand. Furthermore, it is unclear whether MSN will have sufficient resources on hand to be able to compensate Novartis fully for those sales losses. Additionally, as discussed above, Novartis will suffer harms that would not only take place during the pendency of an at-risk launch, but would also extend well beyond the MSN and any follow-on entrants' subsequent withdrawal. Therefore, even setting aside the many harms that Novartis would experience that do not emanate directly from lost sales or lower prices, MSN's entry will cost Novartis more than MSN would stand to make upon entry.

V. CONSIDERATION OF PUBLIC INTEREST

80. From an economic perspective, the U.S. patent system provides economic incentives to innovators that, in the context of the pharmaceutical industry, help drive investment in research and development projects for novel treatments and therapies. Patent protection for novel therapeutic products like Entresto® afford innovative drug companies the ability to recoup their substantial investments in research and development. Therefore, as a general matter, this factor weighs in favor of the patentee (whether the patentee be the original inventor or a party who has acquired interest in the patent) when the public interest is considered in injunction contexts.

81. Additionally, in this particular context, and as discussed in Section III above, there will be additional harm to individuals with heart failure with the launch of "at-risk" generic sacubitril/valsartan products. I understand that if Novartis accelerates it reduction to investments in driving education and conversation around heart failure and Entresto®, there may be prescribers that are ultimately less comfortable or familiar with using a sacubitril/valsartan product and, thus, some patients will be less likely to be prescribed that treatment.[160] For instance, certain clinicians, cardiologists, and PCPs who treat heart failure patients with ACEis and ARBs (even though treatment guidelines specify they should be on Entresto®[161]) may continue to do so. Additionally, any accelerated reduction in Novartis's investments in patient support programs would negatively impact individuals with heart failure – both patients who are currently on Entresto® and patients who will start on treatment that may now stop prematurely without support from Novartis. The

[160] Conversation with Kristin Miller.
[161] *See* Section II.B.2.

harms to the public would, all else being equal, weigh in favor of granting an injunction that would enjoin sales of "at-risk" generic sacubitril/valsartan products.

I declare under penalty of perjury that the foregoing is true and correct.

August 2, 2024

Christopher A. Vellturo, Ph.D.

EXHIBIT 1

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EXHIBIT 2

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EXHIBIT 15

Exhibit 15
Generic Pharmaceutical Manufacturers' Annual Reports Summary
2023 – 2024[1]

Company	Rupees (millions)	Margin (%)[2]	Estimated MSN 2024 Profit ($ millions)[3]
Aurobindo[4]			
[1] Revenue From Operations	₹ 290,019		
[2] Gross Profit	₹ 163,990	56.5%	*$424*
[3] EBITDA	₹ 58,430	20.1%	*$151*
[4] Net Profit Before Tax	₹ 43,800	15.1%	*$113*
[5] Net Profit	₹ 31,690	10.9%	*$82*
Torrent Pharmaceuticals[4]			
[6] Revenue From Operations	₹ 107,280		
[7] Gross Profit	₹ 80,410	75.0%	*$562*
[8] EBITDA	₹ 34,140	31.8%	*$239*
[9] Net Profit Before Tax	₹ 23,520	21.9%	*$164*
[10] Net Profit	₹ 16,560	15.4%	*$116*
Sun Pharmaceuticals			
[11] Revenue From Operations	₹ 484,969		
[12] Gross Profit	₹ 370,958	76.5%	*$574*
[13] EBITDA	₹ 130,000	26.8%	*$201*
[14] Net Profit Before Tax	₹ 110,879	22.9%	*$171*
[15] Net Profit	₹ 95,764	19.7%	*$148*

Notes:

1. The most recent annual reports of the three companies listed in this exhibit report financial data from April 1, 2023 to March 31, 2024, see https://www.aurobindo.com/api/uploads/resultsannouncement/AFR-31032024.pdf; https://www.aurobindo.com/api/uploads/resultsannouncement/LtrToSEsInvestorPresentation25052024.pdf; https://www.torrentpharma.com/pdf/download/AR-2023-24.pdf; https://sunpharma.com/wp-content/uploads/2024/07/SPIL-Annual-Report-2023-24.pdf; https://sunpharma.com/wp-content/uploads/2024/07/SPIL-IR-Presentation-July2024-INR.pdf.
2. I calculate margins by dividing each company's earnings or profit measures by its Revenue from Operations.
3. MSN is a privately held company and does not publicly report profits. MSN does, however, report annual revenues of $750 million in 2023. I therefore estimate a possible range for MSN's profits by multiplying the estimated margins for Aurobindo, Torrent Pharmaceuticals, and Sun Pharmaceuticals by $750 million. See https://www.msnlabs.com/our-achievements.html.
4. Aurobindo and Torrent Pharmaceuticals report certain results in crore rupees, see https://www.aurobindo.com/api/uploads/resultsannouncement/LtrToSEsInvestorPresentation25052024.pdf; https://www.torrentpharma.com/pdf/download/AR-2023-24.pdf. One crore rupees is equal to ten million rupees, see https://www.dictionary.com/browse/crore.

Sources:

[1], [4]-[5]: https://www.aurobindo.com/api/uploads/resultsannouncement/AFR-31032024.pdf, p. 9.
[2]-[3]: https://www.aurobindo.com/api/uploads/resultsannouncement/LtrToSEsInvestorPresentation25052024.pdf, p. 13.
[6]-[10]: https://www.torrentpharma.com/pdf/download/AR-2023-24.pdf, p. 142.
[11], [13]-[15]: https://sunpharma.com/wp-content/uploads/2024/07/SPIL-Annual-Report-2023-24.pdf, pp. 5, 25, 214.
[12]: https://sunpharma.com/wp-content/uploads/2024/07/SPIL-IR-Presentation-July2024-INR.pdf, p. 47.

EXHIBIT 16

quantitative economic solutions

CHRISTOPHER A. VELLTURO
Founder and President

Over the course of his career, Dr. Vellturo has performed a wide variety of economic and econometric analyses and provided expert testimony in the context of mergers and acquisitions, antitrust litigation, intellectual property litigation and numerous other matters spanning a broad array of industries. Dr. Vellturo has testified on economics-related matters in numerous U.S. District Courts, as well as at the Canadian Competition Bureau, and before arbitral tribunals acting under the rules of arbitration of the American Arbitration Association. He has appeared before the U.S. Department of Justice, the Federal Trade Commission, various states' Attorneys General offices, the Federal Reserve Bank Board of Governors, and numerous other regulatory agencies on merger-related issues and other antitrust matters. Dr. Vellturo has also made appearances at hearings before the European Commission, and other antitrust enforcement agencies around the world. To date, he has performed economic analyses in over one hundred merger matters, in excess of seventy antitrust actions, and well over one hundred intellectual property actions.

Dr. Vellturo has taught graduate-level economics at Boston University's School of Management.

Prior to forming Quantitative Economic Solutions, LLC (QES), Dr. Vellturo was a Principal at Analysis Group/Economics (AG/E) and a Senior Vice President and member of the Board of Directors at National Economic Research Associates (NERA).

Dr. Vellturo has published on a variety of topics, including merger and acquisition-related efficiencies, price discrimination, differentiated product analysis and market definition. His research has appeared in leading academic journals, including *Antitrust*, the *Antitrust Law Journal*, and the *Journal of Economics and Management Strategy*. Dr. Vellturo is a recipient of the Bradley Fellowship in Public Economics and has served as a referee for *American Economic Review* and *Rand Journal of Economics*.

A Ph.D. graduate in Economics from the Massachusetts Institute of Technology, Dr. Vellturo also holds a Sc.B. in Applied Mathematics and Economics from Brown University, where he graduated *magna cum laude* and *Phi Beta Kappa*.

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EDUCATION

1989 Ph.D. in Economics, Massachusetts Institute of Technology
Primary Fields: Econometrics, Industrial Organization
Secondary Fields: Public Finance, Game Theory, Law and Economics

1983 Sc.B. in Applied Mathematics and Economics (*magna cum laude*), Brown University

PROFESSIONAL EXPERIENCE

2002-Present **Quantitative Economic Solutions, LLC**
Founder and President – Direct research on microeconomic issues in litigation and non-litigation matters. Areas of particular focus include: antitrust, regulation, and damages assessment in intellectual property and contract matters.

2008-2015 **Boston University, School of Management**
Instructor – Department of Finance & Economics

2000-2002 **Analysis Group/Economics**
Principal – Direct research and provide expert testimony on a variety of microeconomic issues with particular emphasis on antitrust, intellectual property, and mergers and acquisitions. Expert reports and testimony presented in U.S. District Court. Presented antitrust economic analyses to Federal Trade Commission, U.S. Department of Justice, Federal Reserve Bank Board of Governors and the European Commission.

1996-2000 **National Economic Research Associates, Inc.**
Senior Vice President (1999-2000)
Vice President (1996-1999)

1991-1996 **Cambridge Economics, Inc.**
Director – Directed research and provided expert testimony on a variety of microeconomic issues with particular emphasis on antitrust, intellectual property, and mergers and acquisitions. Prior expert testimony provided in U.S. District Court and before the American Arbitration Association. Presented antitrust economic analyses to U.S. Department of Justice, Federal Trade Commission (Antitrust Division), state Attorneys General offices, and the Federal Reserve Bank Board of Governors.

1989-1991 **National Economic Research Associates, Inc.**
Senior Consultant – Directed and performed research relating to issues of antitrust, intellectual property, mergers and regulation.

1987 **Department of Economics, M.I.T.**
Teaching Assistant – Undergraduate econometrics.

1985-1989 **Dean Ann F. Friedlaender, M.I.T.**
Research Associate – Participated in research relating to transportation pricing and capital allocation responses to regulatory changes.

1983-1985 **National Economic Research Associates, Inc.**
Research Associate – Conducted research on a wide variety of issues including antitrust, railroad rate setting, optimal landfill pricing, and PCB and asbestos abatement strategies.

AWARDS AND PROFESSIONAL ACTIVITIES

1987-1989	Recipient, Bradley Fellowship in Public Economics
1986	M.I.T. Departmental Fellowship
1983	Phi Beta Kappa, Brown University
1983	Sigma Xi, Brown University
Present	Journal Referee for *American Economic Review* and *Rand Journal of Economics*
Present	Member, American Economic Association
Present	Member, American Bar Association

TESTIFYING HISTORY (PAST FOUR YEARS)

- *Mylan Pharmaceuticals, Inc. v. Novo Nordisk A/S*
  United States Patent and Trademark Office before the Patent Trial and Appeal Board, Case IPR2023-00724

- *Novo Nordisk Inc. and Novo Nordisk A/S v. Orbicular Pharmaceutical Technologies PVT. LTD., et al.*
  United States District Court for the District of Delaware, C.A. No. 1:22-cv-00856-CFC

- *Novartis Pharmaceuticals Corporation and Astex Therapeutics Ltd. v. MSN Pharmaceuticals, Inc. and MSN Laboratories PVT Ltd.*
  United States District Court for the District of Delaware, C.A. No. 21-870 (GBW)

- *Astellas Pharma Inc., et al. v. Lupin ltd., et al.*
  United States District Court for the District of Delaware, C.A. No. 23-819-GBW-CJB

- *Amgen Inc. and Amgen Manufacturing, Limited v. Sandoz Inc.*
  United States District Court for District of New Jersey, C.A. No. 1:23-cv-02406-CPO-EAP

- *Genzyme Corporation and Aventis Inc. v. Novartis Gene Therapies, Inc., and Novartis Pharmaceuticals Corporation*
  United States District Court for the District of Delaware, C.A. No. 21-1736 (RGA)

- *Novartis Pharmaceuticals Corporation v. Lupin Inc.*
  United States District Court for the District of Delaware, C.A. No. 21-1105-MN
  Novartis Pharmaceuticals Corporation and Dana-Farber Cancer Institute, Inc. v. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.
  United States District Court for the District of Delaware, C.A. No. 21-1106-MN
  Novartis Pharmaceuticals Corporation and Dana-Farber Cancer Institute, Inc. v. Lotus Pharmaceutical Co., Ltd., Teva Pharmaceuticals Development, Inc.
  United States District Court for the District of Delaware, C.A. No. 21-1107-MN

- *Plastipak Packaging, Inc. v. Nestle Waters North America, Inc., Operating as BlueTriton Brands, Inc.*
  United States District Court for the Eastern District of Virginia, C.A. No. 1:20-cv-1288

- *Speyside Medical, LLC v. Medtronic CoreValve LLC, and Medtronic, Inc.*
  United States District Court for the District of Delaware, C.A. No. 20-361-LPS

- *PRCM Advisers LLC, Pine River Capital Management L.P., and Pine River Domestic Management L.P. v. Two Harbors Investment Corp.*
  United States District Court for the Southern District of New York, C.A. No. 1:20-cv-05649-LAK

- *Nevro Corp. v. Mayo Foundation for Medical Education and Research; and Venturi Group, LLC (Now Flathead Partners, LLC)*
  American Arbitration Association, Case No. 01-22-0002-8455

- *Microspherix LLC v. Merck Sharp & Dohme Corp., Merck Sharp & Dohme B.V., Organon USA, Inc., and Organon USA, LLC*
  United States District Court for the District of New Jersey Camden Vicinage, C.A. No. 2:17-cv-03984-RMB-JBC

- *Novo Nordisk Inc. and Novo Nordisk A/S v. Teva Pharmaceuticals, Inc. (F/K/A Teva Pharmaceuticals Development, Inc.) and Teva Pharmaceuticals USA, Inc.*
  United States District Court for the District of Delaware, C.A. No. 21-1782 (CFC)

- *Alacritech, Inc., v. Tier 3, et al.* (2:16-cv-00693-RWS-RSP (Lead Case)), *Wistron Corporation, et al.* (2:16-cv-00692-RWS -RSP), *Dell Inc.* (2:16-cv-00695-RWS-RSP), Defendants, and *Intel Corporation, Cavium, Inc.*, Intervenors
  United States District Court for the Eastern District of Texas Marshall Division

- *Plastipak Packaging, Inc. v. CG Roxane, LLC*
  United States District Court for the Southern District of Texas, Civil Action No. 4:20-cv-00356

- *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*
  United States District Court for the District of California Southern Division, C.A. No. 8:20-cv-00847 (DOC) (JDE)

- *Harry Ploss, et al. v. Kraft Foods Group, Inc. and Mondelez Global LLC*
  United States District Court for the Northern District of Illinois Eastern Division, Case No. 15-cv-2937

- *Indivior Inc., Indivior UK Limited, and Aquestive Therapeutics, Inc. v. Alvogen Pine Brook LLC*
  United States District Court for the District of New Jersey, C.A. No. 17-cv-07106 (KM) (CLW)

- *Astellas Pharma Inc., Astellas Ireland Co., LTD., and Astellas Pharma Global Development, Inc. v. Sandoz Inc., et al.*
  United States District Court for the District of Delaware, C.A. No. 20-CV-01589

- *Teva Pharmaceuticals International GMBH and Teva Pharmaceuticals USA, Inc. v. Eli Lilly and Company*
  United States District Court for the District of Massachusetts, C.A. No. 1:18-cv-12029-ADB

- *Novartis Pharmaceuticals Corporation v. Mylan Pharmaceuticals, Inc.*
  United States District Court for the District of Delaware, C.A. No. 1:19-cv-1118-LPS

- *Novartis Pharmaceuticals Corporation v. Accord Healthcare, Inc., et al.*
  United States District Court for the District of Delaware, C.A. No. 1:18-cv-1043-KAJ

- *United Services Automobile Association v. PNC Bank, N.A.*
  United States District Court for the Eastern District of Texas Marshall Division, Case No. 2:21-cv-0246-JRG

- *Advantest America, Inc.; and Advantest Test Solutions, Inc. v. Samer Kabbani; Lattice Innovation, Inc.; AEM Holdings LTD; and Wavem US Inc.*
  Before the JAMS Arbitration Panel, Reference No: 1200057839

- *Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. v. Nevro Corp.*
  United States District Court for the District of Delaware, C.A. No. 16-1163 (CFC)

- *Astellas US LLC; Astellas Pharma US, Inc.; and Gilead Sciences Inc. v. Hospira, Inc.*
  United States District Court for the District of Delaware, C.A. No. 18-1675-CFC-CJB (Consolidated)

- *United Services Automobile Association v. PNC Bank, N.A.*
  United States District Court for the Eastern District of Texas Marshall Division, Case No. 2:20-cv-00319-JRG

- *Anthony Colucci, Vanessa Lorraine Skipper, Individually and on Behalf of Those Similarly Situated v. Health First, Inc.*
  United States District Court for the Middle District of Florida, C.A. No. 6:21-cv-00681-RBD-GJK

- *I-Mab v. Tracon Pharmaceuticals, Inc.*
  ICC Case No. 25372/MK

- *Novo Nordisk Inc. and Novo Nordisk A/S v. Sandoz Inc.*
  United States District Court for the District of Delaware, C.A. No. 20-00747-CFC

- *Indivior Inc. and Indivior UK Limited v. Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc.*
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EXHIBIT 17

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Conversations

Ms. Kristin Miller
Mr. Robert Rubinsky
Mr. Daniel DiMeo
Ms. Ashley Reid
Mr. Amogh Purandare

Legal Filings

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Ex. 7, HF Market TRx_LaunchToDate.xlsx
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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that true and correct copies of the foregoing document were caused to be served on August 2, 2024 on the following counsel in the manner indicated below.

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